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Research Article

A Randomised Controlled Trial to Evaluate the Efficacy of Pradarari Churna and Pushyanuga Churna in the Management of Asrigdara (Dysfunctional Uterine Bleeding)

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Abstract

Introduction: Asrigdara, correlated with Dysfunctional Uterine Bleeding (DUB), is a common gynaecological disorder characterised by abnormal uterine bleeding without detectable pathology. This study aimed to clinically evaluate and compare the efficacy of *Pradarari Churna and Pushyanuga Churna* in their management. Materials and Methods: 40 patients diagnosed with A*srigdara* (DUB) were randomly divided into two groups of 20 each. Group A received *Pradarari Churna* (500 mg BD) with *Sitajala*, and Group B received *Pushyanuga Churna (*500 mg BD) with *Tandulodaka* and *Madhu* for two months.

Results: Both groups showed significant improvement in all clinical parameters (p<0.001). Overall symptomatic relief was 61.48% in Group A and 66.17% in Group B.

Conclusion: Both formulations are safe and effective. *Pradarari Churna* showed comparable efficacy to the classical *Pushyanuga Churna* in addressing symptoms and underlying doshic imbalances.

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KEYWORDS: Asrigdara, Dysfunctional Uterine Bleeding, Pradarari Churna, Pushyanuga Churna, Randomised Controlled Trial.

1. INTRODUCTION

The health of a woman is foundational to the strength of her family and community. Modern lifestyle stress has contributed to a rise in Dysfunctional Uterine Bleeding (DUB), now termed Abnormal Uterine Bleeding-Ovulatory dysfunction (AUB-O). It affects 3% to 30% of reproductive-age women globally; in India, the prevalence is approximately 17.9[2]%.

Ayurveda classifies this condition as Asrigdara, viewing it as a *Rakta Pradoshaja Vyadhi* caused primarily by the vitiation of *Rakta Dhatu* due to *Pittavrita Apana Vayu*[3]. While modern medicine offers hormonal and surgical interventions like hysterectomy, these often carry risks or provide only temporary relief [4]. Ayurveda provides a holistic approach targeting the root cause (*Samprapti Vighatana*). *Pradarari Churna* and *Pushyanuga Churna* were selected for this study due to their *Stambhaka* (astringent) and *Raktastambhana* (hemostatic) properties[5].

2. AIMS AND OBJECTIVES

- **Aim:** To evaluate the efficacy of *Pradarari Churna* and *Pushyanuga Churna* in the management of Asrigdara (DUB).

Objectives

- To evaluate the efficacy of *Pradarari Churna*[6] in *Asrigdara.*
- To evaluate the efficacy of *Pushyanuga Churna* in *Asrigdara*
- To compare the efficacy between the two formulations

Hypothesis

- **H3 (Alternative Hypothesis):** There is an equal statistically significant effect of both *Pradarari Churna* and *Pushyanuga Churna* in the management of Asrigdara[19].

3. METHODOLOGY

SOURCES OF DATA

Type of Study

This is a Randomized Controlled Trial (RCT) designed to evaluate the efficacy of the interventions in patients diagnosed with ***Raktapradara.***

A total of 40 patients meeting the inclusion criteria were selected. These patients were randomly allocated into two equal groups:

- **Group A (Trial Group)** – 20 patients
- **Group B (Control Group)** – 20 patients

Sampling Technique

Patients were randomly assigned to either group using the coin toss method.

Table 1: Intervention for Group A and Group B

		Group A	Group B
1	**Drug Name**	*Pradarari churna*[6]	*Pushyanag Churna*
2	**Type**	*Churna*	*Churna*
3	**Drug form**	Solid	Solid
4	**Seven kal**	at the commencement of the meal.	at the commencement of the meal.
5	**Matra**	500 mg BD	500 mg BD
6	***Schedule***	2 times daily at the commencement of a meal	2 times daily at the commencement of a meal
7	***Kalavadhi***	From1st day of the menses to throughout the cycle.	From1st day of the menses to throughout the cycle.
8	***Anupan***	Sitajal	Tandulodaka and Honey

Table 2: Follow-Up for Group A and Group B

	Group I	Group II
Duration of Treatment	2 Months	2 Months
During Treatment Follow-Up	the 1st, 5th and 8th days of each menstrual cycle during the 2-month treatment period	the 1st, 5th and 8th days of each menstrual cycle during the 2- month treatment period
After Treatment Follow-Up	the 1st, 5th and 8th days of the post-treatment menstrual cycles, or within 2 months after administering the dose	the 1st, 5th and 8th days of the post-treatment menstrual cycles, or within 2 months after administering the dose

Duration of Study

Treatment duration: 2 months, Follow-up duration: 2 months, Total study duration: 4 months.

Study Design:

Randomised Controlled Clinical Trial

⇓

Duly signed & dated consent form by subjects will participate.

⇓

Screening of subjects according to baseline assessment &

⇓

inclusion & exclusion criteria

⇓

Randomization allocation of group

⇓

Group A Trail Group (20 patients) | Group B Control Group (20 Patients)

Pradaradi Churna Pushyanag Churna

↓

Starting from the 1st day of meses to throughout the cycle.
Continued for 2 consecutive months.

The 1st, 5th and 8th days of each menstrual cycle during the 2-month treatment period follow up take during treatment

↓

On the 1st, 5th and 8th days of the post-treatment menstrual

↓

cycles, or within 2 months after treatment, follow-up is taken.

Observation, Statistical Analysis, Conclusion and Results.

SELECTION CRITERIA
DIAGNOSTIC CRITERIA-
Patient fulfilling any two or more of the following criteria, based on investigation findings

- Prolonged bleeding>7days
- Excessive bleeding>3-5pads completely soaked/day, with or without clots
- Intermenstrual bleeding <21days
- Weakness, pallor, pain in the lower abdomen

With or without malaise, nausea and vedana (painful menstruation).

INCLUSION CRITERIA

- Age group: 16-45 years
- Excessive bleeding during menstruation with change of7-8 fully soaked pads/day
- Prolonged bleeding>7days
- Intermenstrual bleeding<21days
- Hemoglobin% >8gm/dL
- Married and unmarried women

EXCLUSION CRITERIA

- Genetic bleeding disorder (Van Willebrand's disease) and other systemic coagulative disorders.
- Medical conditions: Acute PID, Liver disease, Chronic renal disease, HIV, TB, DM, H.T.N and Thyroid disorder.
- Fibroiduterus
- Uterinepolyps, Adenomyosis, Tumors.
- Pelvic endometriosis
- Medication: OCP, Warfarin, Enoxaparin, Apixaban and other anticoagulant drugs.
- Patient with IUCD
- Patient with chronic illness.
- Postmenopausal bleeding.

Withdrawal of subject-
During the trial patient was not willing to continue the treatment. Patient absent for follow-up
Intervention
Patients were assessed before and after treatment as per assessment criteria, and data were recorded in a special case sheet proforma.
The patient having full right to quit the study at any time.
The confidential data mentioned confidentially was subjected to statistical analysis.

ASSESSMENT CRITERIA:
Assessment will be made based on the subjective and objective parameters before, during and after treatment.

Subjective Parameter:

Table no 3: Pramana of Rajasrava

Bleeding amount in number of pads/days	Grade
a)2-3 pads fully soaked	0
b) 4 pads fully soaked	1
c)5-6 pads fully soaked	2
d)7-8 pads fully soaked	3

Table 4: Intermenstrual bleeding

Intermenstrual bleeding	Description	Grade	B. T	A. T
Absent	No Intermenstrual bleeding	0		
Mild	Spotting between cycles	1		
Moderate	Bleeding lasting for 2-3 days between 2 cycles	2		
Severe	Bleeding lasting >3 days between 2 cycles	3		

Objective Parameter:

Objective blood loss(>80mL) by Pictorial Blood Assessment Chart (PBAC):

Table 5: Pramana of Rajasrava

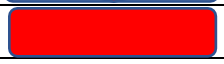
Degree of saturation of sanitary pads used during menstruation/day	Assessment	Grades
	Lightly stained	01
	Moderately saturated	05
	Completely soaked	20

Table 6: Clots

Clots	Score
Large clots (more than 1inch in diameter)	05
Small clot	01

Interpretation: Totals more than 100 points per menstrual cycle indicate >80mL objective blood loss

Table 7: Assessment of Amount of Blood Loss (AOBL)

Assessment of Amount of Blood Loss (AOBL)	Score	Grade
≤ 80 gm/dl	0	Nil
81 – 100 gm/dl	1	Mild
101 – 120 gm/dl	2	Moderate
> 120 gm/dl	3	Severe

Table 8: Duration of bleeding or menstrual phase

Duration of bleeding in number of days	Grade
a)3-5 days	0
b)6-7 days	1
c)7-8 days	2
d)>8 days	3

Table 9: Pain in the lower abdomen/Backache

Visual analogue scale	Pain	Grade
0	No pain	0
1-3	Mild pain	1
4-6	Moderate pain	2
7-10	Severe pain	3

Table 10: Overall assessment criteria

Sr. No.	Criteria	Improvement Grade
1	75% to 100%	Marked
2	50% to 74%	Moderate
3	25% to 49%	Mild
4	00% to 24%	Poor

INVESTIGATIONS

1. USG Pelvis
2. Complete Blood Count
3. BT, CT

COMPARATIVE ANALYSIS

Statistical Analysis (By Mann – Whitney test)

Table 11: Praman of Rajastrav (Bleeding amount in number of pads /day) By Mann – Whitney test

Symptom	**Praman of Rajastrav (**Bleeding amount in number of pads /day**)**
Mean difference score, Group A	1.33
Mean difference score, Group B	1.55
S.D. (±) of Group A	0.65
S.D. (±) of Group B	0.82
S.E. (±) of Group A	0.14
S.E. (±) of Group B	0.18
U	233
U ‘	167
% Improvement of Group A	63.41
% Improvement of Group B	68.89
P	0.37

Mean difference of Group A is not much more than the mean difference of Group B, and p value is greater than the significance level alpha = 0.05, which shows efficacy of Pradarari churna (Group A) is not significant than Pushyanuga churna (Group B) forPraman of Rajastrav (number of pads).

Table 12: Intermenstrual bleeding By Mann – Whitney test

Symptom	Intermenstrual bleeding
Mean difference score, Group A	0.45
Mean difference score, Group B	070
S.D. (±) of Group A	0.51
S.D. (±) of Group B	0.57
S.E. (±), of Group A	0.11
S.E. (±), of Group B	0.12
U	244.4
U ‘	155.5
% Improvement of Group A	60.00
% Improvement of Group B	60.87
P	0.22

Mean difference of Group A is not much more than the mean difference of Group B, and the p value is greater than the significance level alpha = 0.05, which shows efficacy of Pradarari churna (Group A) is not significant than Pushyanuga churna (Group B) forIntermenstrual bleeding.

Table 13: Praman of Rajastrav (saturation of pads) by Mann–Whitney test

Symptom	Praman of Rajastrav (saturation of pads)
Mean difference score, Group A	1. 55
Mean difference score, Group B	1.30
S.D. (±) of Group A	0.65
S.D. (±) of Group B	0.82
S.E. (±), of Group A	0.14
S.E. (±), of Group B	0.18
U	233
U ‘	167
% Improvement of Group A	63.41
% Improvement of Group B	68.89
P	0.37

Mean difference of Group A is not much more than the mean difference of Group B, and the p value is greater than the significance level alpha = 0.05, which shows efficacy of Pradarari churna (Group A) is not significant than Pushyanuga churna (Group B) forPraman of Rajastrav (saturation of pads).

Table: 14 Clots by Mann – Whitney test

Symptom	Clots
Mean difference score, Group A	0.90
Mean difference score, Group B	1.15
S.D. (±) of Group A	0.64
S.D. (±) of Group B	0.81
S.E. (±), of Group A	0.14
S.E. (±), of Group B	0.18
U	232.5
U ‘	165
% Improvement of Group A	56.25
% Improvement of Group B	62.16
P	0.37

Mean difference of Group A is not much more than the mean difference of Group B, and the p value is greater than the significance level alpha = 0.05, which shows efficacy of

Pradarari churna (Group A) is not significant than Pushyanuga churna (Group B) for Clots.

Table 15: Duration of Bleeding by Mann – Whitneytest

Symptom	Duration of Bleeding
Mean difference score, Group A	1.65
Mean difference score, Group B	1.80
S.D. (+) of Group A	0.67
S.D. (+) of Group B	0.69
S.E. (+), of Group A	0.15
S.E. (+), of Group B	0.15
U	217.5
U ‘	182.5
% Improvement of Group A	67.35
% Improvement of Group B	73.47
P	0.63

Mean difference of Group A is not much more than the mean difference of Group B, and the *p* value is greater than the significance level alpha = 0.05, which shows efficacy of Pradarari churna (Group A) is not significant than Pushyanuga churna (Group B) for Duration of Bleeding.

Table 16: Pain in the lower abdomen / Backache by Mann – Whitney test

Symptom	Pain in the lower abdomen / Backache
Mean difference score, Group A	1.10
Mean difference score, Group B	1.60
S.D. (+) of Group A	0.78
S.D. (+) of Group B	0.28
S.E. (+), of Group A	0.17
S.E. (+), of Group B	0.18
U	264
U ‘	136
% Improvement of Group A	53.66
% Improvement of Group B	62.75
P	0.08

Mean difference of Group A is not much more than the mean difference of Group B, and the p value is greater than the significance level alpha = 0.05, which shows efficacy of Pradarari churna (Group A) is not significant than Pushyanuga churna (Group B) for Pain lower abdomen / Backache.

Table 17: To compare Group A Vs Group B mean difference across symptoms

Symptom	Group A	Group B
Praman of Rajastrav (Bleeding)	1.33	1.55
Intermenstrual bleeding	0.45	0.70
Praman of Rajastrav (Saturation)	1.55	1.30
Clots	0.90	1.15
Duration of Bleeding	1.65	1.80
Pain in the lower abdomen / Backache	1.10	1.60

Graph:1 Comparision of mean difference scores

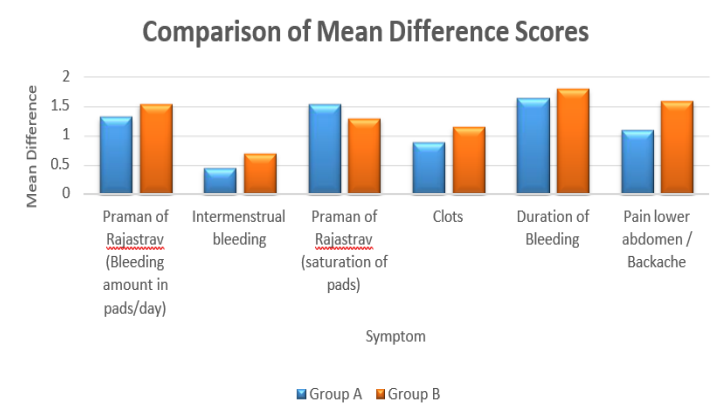
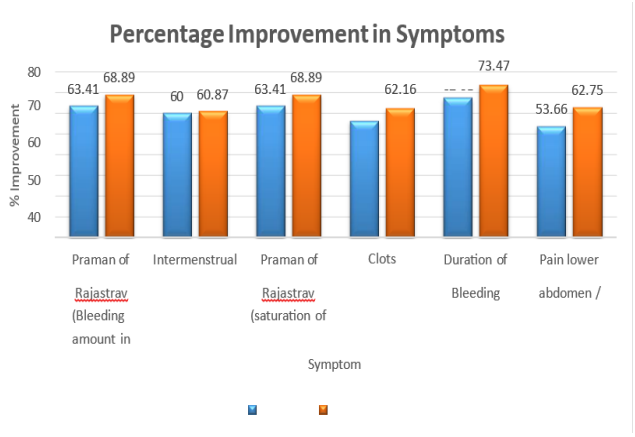


Table: 18 % Improvement Chart

Symptom	Group A	Group B
Praman of Rajastrav (Bleeding)	63.41	68.89
Intermenstrual bleeding	60.00	60.87
Praman of Rajastrav (Saturation)	63.41	68.89
Clots	56.25	62.16
Duration of Bleeding	67.35	73.47
Pain in the lower abdomen / Backache	53.66	62.75

Graph: 2 Percentage Improvement in Symptoms



Observation and Results

- **Demographics:** The highest incidence (40%) was in the 26–35 age group. 67.5% of participants were married.

Clinical Improvement (Within Groups):

- **Bleeding Amount:** Significant reduction in both groups (p=0.00014)
- **Duration:** Reduced from 2.45 mean score to 0.80 in Group A and 0.65 in Group B
- **Haemoglobin:** showed a significant increase in both groups (p<0.001).

Comparative Efficacy:

- Group B (*Pushyanuga Churna*) showed slightly higher relief in duration (73.47% vs. 67.35%) and bleeding amount (68.89% vs. 63.41%).

- However, the **Mann-Whitney test** showed no statistically significant difference between the two groups across all symptoms ($p > 0.05$)

4. DISCUSSION

Asrigdara involves a disruption of *Artava Pravritti*, regulated by *Apana* and *Vyana Vayu*. *Pradarari Churna* works through its ingredients: *Rasanjana* (purifies blood and arrests bleeding), *Ashwagandha* (balances *Vata* and supports reproductive health), and *Swarjikshara* (improves metabolism and supports *Apana Vayu*).

The study found that while both drugs are highly effective, *Pushyanuga Churna* consistently showed a marginally higher percentage of improvement. The lack of a statistically significant difference between the groups suggests that *Pradarari Churna* is a viable and effective alternative to the traditional standard of care.

5. CONCLUSION

The trial successfully validates the effectiveness of both *Pradarari Churna* and *Pushyanuga Churna* in managing Asrigdara (DUB). Both formulations significantly reduced excessive bleeding, shortened menstrual duration, and improved haemoglobin levels. *Pradarari Churna* is proven to be a safe, effective, and holistic therapeutic option.

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