

ORIGINAL RESEARCH ARTICLE

Management of *Asrigdara* in women of Late Reproductive Age Group w.s.r. to AUB: An Open-Label, Randomized, and Parallel Clinical Study

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ABSTRACT

Background: In recent times, menstrual and hormonal irregularities have become more common in women of all ages. Menstrual conditions with bleeding more than normal, for prolonged period, or irregular bleeding are included in Abnormal Uterine Bleeding (AUB). Management in conventional science for the same includes of hormonal management or invasive surgeries which have their own drawbacks. Opting for safer alternative like Ayurveda shows great benefits in the management of AUB.

Objective: The objective of this study was to assess efficacy of Ayurvedic interventions; “*Madhukadi Yoga*” and “*Madhukadi Tailam Matra Basti*” in the management of AUB (*Asrigdara*).

Materials and Methods: An open-label, interventional, and parallel study with 30 participants was conducted and they were randomly divided into two groups. One of which was given *Madhukadi Yoga* orally and *Madhukadi Tailam Matra Basti*, whereas the other group was administered with only oral drug for three consecutive cycles. Evaluation was made on the basis of subjective and objective assessment criteria by applying paired T test before and after completion of the intervention and comparison was made between both groups using statistical tests.

Results: Comparatively better results were obtained among patients receiving both the *Madhukadi Yoga* orally and *Madhukadi Tailam Matra Basti* than the other group.

Conclusion: The findings offer preliminary evidence of the safety and possible advantages of Ayurveda in the treatment of AUB. To suggest the use of these therapies in ordinary clinical practice, more research with larger sample size should be conducted to produce strong proof of their therapeutic potential.

1. INTRODUCTION

Modern mode of living has been responsible in bringing many ailments in reproductive health of women as manifested as menstrual disorders like heavy menstrual bleeding. *Asrigdara* is close relative entity to the condition of HMB. As mentioned by the *Acharya Charak*, *Asrigdara* is *Pradirana of Rajah*, that is, excessive excretion of menstrual blood. *Chakrapani* elaborates the concept of it as a condition of excessive flow of blood in *Anritukaala* (intermenstrual period)^[1]. *Acharya*

Charaka and Sushruta have mentioned it as *Shonitajanyavyadhi*^[2,3] and *Pittaavriteapane Vayu*.^[4,5] In other context, it as a separate disease entity where there is excessive bleeding during *Ritukala* (menstrual phase), that is, *Atipravritti* (excessive) or *Dirghapravritti* (prolonged bleeding) and *Anritukalapravritti* (bleeding during intermenstrual period). Similarly, *Acharya Vagbhat* explained *Raktayoni* and mentioned *Asrigdara* and *Pradar* as its synonyms.^[6]

Abnormal Uterine Bleeding (AUB) affects women of all ages, with late reproductive and peri-menopausal age groups being particularly affected. DUB is caused by dysfunctional H-P-O axis, while hormone replacement therapy and surgical interventions used for its treatment can cause harmful effects. Ayurvedic preparations, such as *Samsodhan*

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therapy and Basti treatment, are considered supreme for managing *Artava*-related disorders. A clinical study evaluated the efficacy of classical preparations *Madhukadi Tailam*^[7] and *Madhukadi Yoga*^[8] for treating *Asrigdara*.

1.1. Samprapti

Vata vitiation is obtained through *Ahara*, *Vihara*, and *Swanidana* practices, while *Raktadhatu Dushti* occurs from excessive consumption of *Amla*, *Lavana*, *Katu*, and *Vidahi Bhojana*. This also vitiates *Pitta* due to similar characteristics with *Rakta*. *Prakupita Vata* increases *Rakta* and *Rajah* due to common *Rasa bhava* or *Rasajatva*, causing irregular or excessive *Rajah* discharge due to vitiated *Vayu*, known as *Asrigdara*.^[9]

Another references have mention excessive *Rajahsra* as a symptom of *Pittavritapanavayu*,^[10] or *Pitta Samyukta Apana Vayu*.^[5]

Since, *Asrigdara* is a form of *Adhoga Raktapitta*, there is reference quoting the involvement of *Vata Dosha* in etiology of *Adhoga Raktapitta*.^[11]

Maharishi Bhela while describing pathological condition states that if *Rakta* goes to abnormal passage (i.e., genital tract), woman suffers from *Pradara*.^[12]

Madhava Nidana, *Bhavaprakash*, and *Yogaratanakara* in their respective texts have mentioned the cause of *Asrigdara* as *Virudhhaahar*, *Madya*, *Vishamasan*, *Ajirna*, *Garbhasrav*, etc.^[13]

1.2. Samprapti Ghataks

- *Dosha* – *Vata (Apanavayu), Pitta Pradha Tridosha*
- *Dushya* – *Rasa, Rakta and Artava*
- *Agni* – *Jathragnimandyata*
- *Adhishtan* – *Garbhashaya, Artavavahi Strotas*
- *Strotas* – *Artavavahi, Rasavahi, Raktavahi*
- *Strotodushti* – *Atipravatti*
- *Rogamarga* – *Abhyantara Rogamarga*

As mentioned above, *Asrigdara* refers to irregular AUB, primarily caused by active or passive congestion, resulting in increased blood in the uterus. It is similar to conditions of menorrhagia and metrorrhagia.

2. MATERIALS AND METHODS

2.1. Study Design

A double arm randomized case-control, open, and comparative clinical study conducted at R.G.G.P.G. Ayurvedic College and Hospital, Paprola.

2.2. Study Participants

From April 2021 to March 2022, a total number of 30 cases were enrolled as per the protocol specifically designed for this clinical trial and randomized in two equal groups. All the participants were recruited from the OPD level and were screened in accordance with the inclusion and exclusion criteria mentioned in the protocol.

2.3. Inclusion Criteria

- i. Those willing for the trial.
- ii. Age group of 35–50 years.
- iii. Either one or all symptoms of *Asrigdara*, that is, *Ritou Atipravitti*, *Anritou pravritti*, and *Deergha Pravritti*.

2.4. Exclusion Criteria

- i. Those not willing for trial.
- ii. Patients with uterine and pelvic pathology such as big fibroid (>5 cm), Ca cervix, and cervical polyp.
- iii. Patients having bleeding sites other than uterus.
- iv. Coagulation disorders.
- v. Women using IUCD and OCPs.
- vi. Uncontrolled medical illnesses.
- vii. If condition of patients deteriorated during trial, they shall be discontinued from trial.

2.5. Study Intervention

Thirty patients were selected for the clinical study in two groups of 15 patients each.

2.5.1. Group I

Madhukadi Yoga – 3 g bid with honey orally for 3 months.
Matra Basti of Madhukadi Tailam – 60 mL/rectum for 8 Days after clearance of menses for three consecutive menstrual cycles.

2.5.2. Group II

Madhukadi Yoga – 3 g bid with honey orally for 3 months.

2.5.3. Duration of trial

Approximately 90 days (three consecutive menstrual cycles).

2.5.4. Follow-up

There were four follow-ups at 1 month interval right after completion of menstrual cycle out of which three follow-ups were during trial and one follow-up without drug after completion of trial.

2.6. Criteria of Assessment

2.6.1. Subjective criteria of assessment

Mentioned in Table 1.

2.6.1.1. Associated features

Mentioned in Table 2.

2.6.2. Objective criteria of assessment

Mentioned in Table 3.

2.6.3. Criteria for final assessment of results

The total effect of therapy was assessed in four groups:

2.7. Assessment of PBAC Score

PBAC score was accessed before treatment, throughout treatment and after a month of drug-free period. Patient was taught about saturation of pads, different size of clots and episodes of flooding. Thus, they were guided to make records of the bleeding accordingly. PBAC score were calculated on every follow-up after clearance of menses and recorded accordingly.^[14]

2.8. Statistical Analysis

The clinical trial was open-label randomized type of study. The information gathered regarding demographic data was shown in percentage. The scores of criteria of assessment were analyzed statistically by application of student paired T test and significance of the results was defined on the value of “p.”

3. RESULTS

A total of 30 patients were enrolled in the study and all the patients completed the study without any dropout. On statistical analysis of collected data with an appropriate test on each criteria, results as mentioned were derived:

3.1. Statistical Analysis of Effect of Therapy in Group I (Oral+Basti)

Shown in Chart 1.

3.2. Effect of Therapy on Objective Criteria of Group I (Oral+Basti)

Shown in Chart 2.

3.3. Effect of therapy on subjective criteria of Group-II (without Basti)

Shown in Chart 3.

3.4. Effect of therapy on objective criteria of Group-II (without Basti)

Shown in Chart 4.

3.5. Intergroup comparison over subjective criteria of assessment

Shown in Chart 5.

3.6. Intergroup comparison of effect of therapy on objective assessment criteria

Shown in Chart 6.

3.7. Overall effects on incidence of associated features

Shown in Chart 7.

3.8. Overall improvement in all patients

Shown in Chart 8.

3.9. Overall Effects on Associated Features Before and After Treatment Group I (Oral+Basti)

Highly significant results in the subjective assessment criteria such as amount, intensity, duration, interval, and pain and in the objective assessment criteria as PBAC score, VAS for pain, and Hb gm% were found among the patients of group I.

Highly significant results in the subjective assessment criteria such as amount, intensity, duration, and pain and in the objective assessment criteria such as PBAC score and VAS of pain were found among the patients of Group-II.

Similarly, significant result was found in interval of menstrual cycle and hemoglobin percentage.

Group I patients had more relief percentage than Group II. Inter-group comparison showed statistically significant results in Group I for amount, interval, and PBAC score of patients and non-significant in other criteria such as intensity, duration, pain, VAS score of pain, and hemoglobin.

Similarly, in associated features, also there were no significant difference in both the groups, that is, both the groups had relatively similar relief in all the associated features.

3.10. Overall Improvement

Group I (Oral+Basti) – None of the patients were markedly improved, 14 out of 15 (93.33%) patients were moderately improved and 1 (6.67%) patient was partially improved.

Group II (Without Basti) – None of the 15 patients were markedly improved, 3 (20%) of the patients were improved moderately and 11 of the patients (73.33%) were partially improved and 1 of the patients (6.67%) was unimproved.

3.11. Drugs Free Follow-Up

After a month of drug-free follow-up, majority of patients in Group I experienced relief in assessment criteria and symptoms, while in Group II, relief was not as improved.

3.12. Adverse Drug Reaction

It was observed that patients could tolerate the treatment quite well and there were no adverse effects noted during the course of trial.

4. DISCUSSION

The main principles of management of *Asrigdara* are *Tridoshashamana* especially, *Vatanulomana*, *Pitta Shamana*, *Raktashodhana*, *Raktasthapan*,^[15] *Raktastambhana*, *Agnideepana*, and *Amapachan*.

Raktasthapan should be done by the usage of hemostatic drugs. However, it should be done after properly diagnosing the *Dosha* involved in the individual.^[16]

Ausadh having *Madhur*, *Tikta*, *Kashaya Ras*, *Madhur Vipaka*, and *Sheet Veerya* are used for the alleviation of *Pitta* and thereby *Rakta Dushiti*.^[17,18]

Treatment as in *Raktapitta* (*Adhoga*), *Raktatisar*, *Raktarshas*, *Guhya Roga*,^[19] and *Garbha Srava*^[20] should be used. In context of treatment of *Raktapitta*, special note has been mentioned that treatment should be focused on *Pachan* of the *Ama* if involved before the *Raktasthapak Chikitsa*.^[21]

There is indication of *Vatanulomana Chikitsa* in case of *Avrit Vata*.^[22]

Asrigdara is a condition of *Dhatukshaya* causing *Mandagni* and thenafter *Vata Prakopa*. *Mandagni* develops *Ama* and *Sama Artava*, causing menstrual disorders like *Asrigdara*. Treatment of *Mandagni* along with vitiated *Vata* is crucial in treatment of this condition.^[23]

The use of *Samsodhan* such as *Basti*^[24] and *Virechan*^[25] has been indicated as these procedures help in extracting the vitiated *Doshas*, normalizing the levels and establishing them into their natural pace.

Asrigdara being a kind of *Adhoga Raktapitta*, treatment of *Vata* is key *Dosha* to be considered for treatment.^[26]

4.1. Probable Mode of Action of Drugs

Most of the constituents of *Madhukadi Tailam* and *Madhukadi Yoga* have *Kashaya*, *Tikta*, *Madhur Rasa*, and *Sheeta Veerya*. The gross action of these *Rasa* was *Tridosha Shamaka* mainly *Pitta Shamaka* which abolishes one of the main *Doshas* responsible for the disease. *Deepana*, *Pachana* action of *Tikta* and *Katu Rasa* corrected the *Agnimandya* which leads to proper formation *Rasa Dhatu* and thereby *Shuddha Artava*. By the virtue of its *Sandhaniya* and *Raktastambhana* properties, *Kashaya Rasa* reduced amount of flow of blood. *Balya*, *Tarpana*, and *Jeevaniya* properties of *Madhura*

Rasa improved the general condition of the patients and toned up reproductive function.

Til Taila is considered as *Uttam Vatanashak* helps in *Yonivisodhana*, *Yonishoolanasha*, *Raktastambhak*, *Vrananashaka*, *Lekhana*, *Vatavikarnashan*, and *Mehanashan Vata-kapha shaman*. Goghreeta also has supreme *Vatapittashamak* property along with *Rasyana*, *Brihmaniya guna*.

Concurrently, the constituents had effects of *Tridoshashamana*, especially *Pittavata shamana*, *Vatanulomana*, *Garbhasayavishodana*, *Raktastambhana-Sthapana*, *Raktavisodhaka*, *Agni-deepana*, and *Amapachak* like properties which were required for the wholesome management of *Asrigdara*. More clarified illustration of probable mode of action of drugs has been schematically presented as below in Figures 1 and 2:

4.2. Probable mode of action of Basti

Anuvasana Basti when given nourishes all the channels after reaching the *Nabhi* (main seat of *Sira* and *Dhamani*).^[27] *Matra Basti* acts locally in the *Pakwasaya*, which is the chief seat of the *Vayu (Apana)* and helps in *Shodhan*, *Shaman*, and *Anulomana* of the vitiated *Vata*.^[28] *Basti Dravya* when given properly, the *Veerya* of the *Basti Dravya* (active principle) acts upon minute channels of *Pakwasaya* and spreads throughout the body. *Basti* nourishes the body as the roots are nourished by the irrigation of water.^[29]

Basti treatment is administered per rectal and the drug thus administered reaches into the rectum and lower parts of large intestine. The *Basti* drug being *Sneha Pradhan*, the drugs infused into the *Snehapaka* easily crosses the mucosal membrane made of polysaccharides and phospholipids due to its affinity. Probable mode of action of the *Matra Vasti* could be based on the theory of Gut-Brain axis regulation of neuro-endocrinological axis in Figure 3.^[30,31]

4.3. Pharmacological Actions of Active Components of Interventional Drugs

Different active components of the drugs that are presumably responsible for the management of *Asrigdara* are mentioned along with their therapeutic actions in Figures 4-10.

5. CONCLUSION

The main principles of management of *Asrigdara* are *Tridosha Shamana* especially, *Vatanulomana*, *Pitta Shamana*, *Raktashodhana*, *Raktastambhana*, *Agnideepana*, and *Amapachan*. The *Madhukadi Yoga* and *Madhukadi Tailam Matra Basti* possessed the above said qualities and helps in management of *Asrigdara*.

Thus, it was concluded that use of *Basti Chikitsa*; *Samsodhan* along with oral administration of the *Ayurvedic* formulation, that is, *Samshaman* showed better results for the management of *Asrigdara* than that seen in the use of *Samshaman ausadh* only. Definitely recurrence of *Asrigdara* was lesser with *Basti* management.

The present study was carried out in small number of *Asrigdara* cases. Large group study may show different conclusions. Hence, the clinical trial should be planned taking large sample for greater duration to show optimum results.

Drug-free follow-up should be for longer period of time to evaluate the sustainability of the results.

6. ACKNOWLEDGMENTS

Nil.

7. AUTHORS' CONTRIBUTIONS

All the authors contributed equally in design and execution of the article.

8. FUNDING

Nil.

9. ETHICAL APPROVALS

Before the initiation of the trial, ethical clearance certification was obtained from the Institutional Ethical Committee (IEC) of R.G.G.P.G. Ayurvedic College and Hospital, Paprola vide IEC No. Ayu/130.

Written consent of the participants was obtained in the IEC-approved consent form. The research work was registered under Clinical Trial Registry-India (CTRI) vide CTRI Reg. no. CTRI/2021/04/032652.

10. CONFLICTS OF INTEREST

Nil.

11. DATA AVAILABILITY

This is an original manuscript and all data are available for only review purposes from principal investigators.

12. PUBLISHERS NOTE

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Table 1: Subjective criteria of assessment

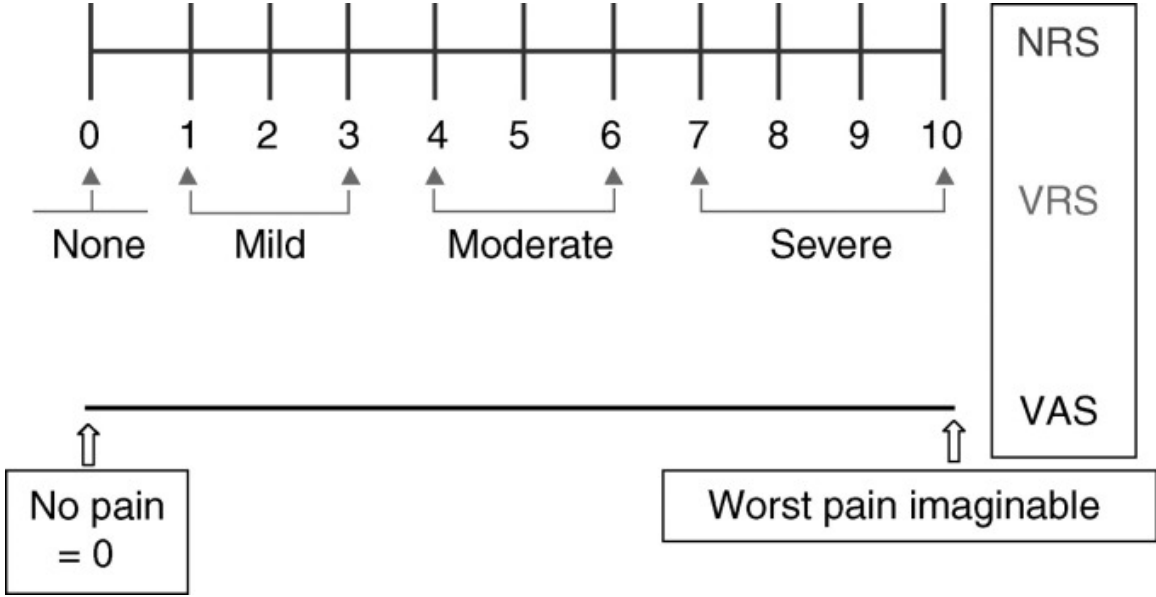
S. No.	Parameter	Criteria	Grade
1.	(Amount (Total Bleeding Score/Day)	Mild bleeding (2–3 pads/day, moderately saturated)	0
		Moderate bleeding (3–4 pads/day, completely saturated)	I
		Spotting (1 pad/day, lightly stained)	II
		Severe bleeding (5–6 pads or more/day, moderate to completely saturated)	III
2.	(Intensity of Flow)	Moderate	0
		Scanty	I
		Heavy (without clots)	II
		Heavy (with clots)	III
3.	(Duration of Bleeding)	3–5 days	0
		6–7 days	I
		8–9 days	II
		>9 days	III
4.	(Intermenstrual period)	28–35 days	0
		24–27 days	I
		20–23 days	II
		<20 days or >35 days	III
5.	(Pain during Menstruation)	No pain	0
		Mild pain, women complain of pain, but do not required any drug for relief.	I
		Moderate pain, women complain, of pain; takes one or two doses of drug for relief pain do not affect routine work.	II
		Severe pain, women complain of pain, takes 3–4 doses of drug for relief. The pain influences general activity.	III
6.	 Visual Analogue scale		
		No pain	0
		Mild pain	1–3
		Moderate	4–6
		Severe	7–10

Table 2: Associated features

S. No.	Criteria	Present	Absent
1.	<i>Angamarda</i> (body ache)		
2.	<i>Vedana</i> (lower back/pelvic region pain)		
3.	<i>Daurbalya</i> (Generalized debility)		
4.	<i>Bhrama</i> (Mental confusion)		
5.	<i>Murchha</i> (Unconsciousness)		
6.	<i>Tama</i> (Blurring of vision)		
7.	<i>Trisha</i> (increased thirst)		
8.	<i>Daha</i> (hot flushes)		
9.	<i>Pralaap</i> (Delirium)		
10.	<i>Tandra</i> (Drowsiness)		
11.	<i>Pandu</i>		

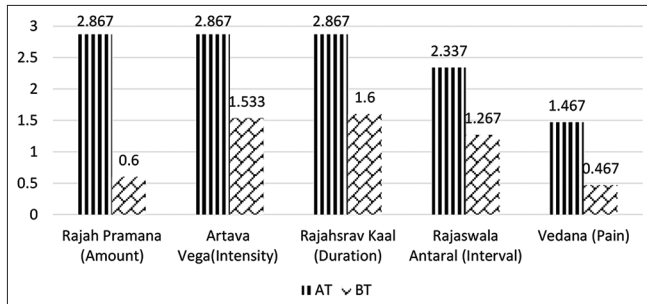
Table 3: Objective criteria of assessment

1.	PBAC scoring system	Nil	0
		For each lightly stained pad and each small clot	1 point each
		For each moderately stained pad; for each large clot or each episode of flooding	5 points each
		For each completely saturated pad	20 points each
	Total PBAC score	Scanty	0–50
	interpretation (Higham <i>et al.</i> 1990)	Normal	50–100
		Heavy menstrual bleeding	>100
2.	Hemoglobin	Normal	>10 g%
		Anemic	<10 g%

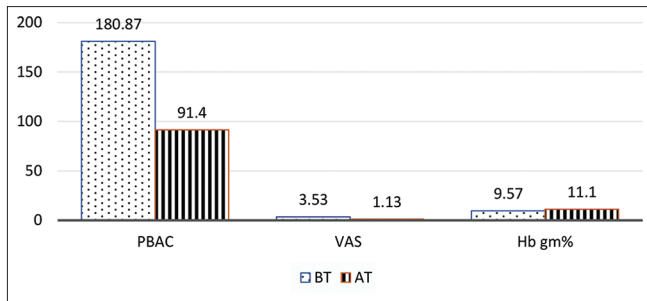
Table 4: Criteria for final assessment of results

1.	Markedly improved	Patients showing more than 75% relief in above mentioned symptoms.
2.	Moderately improved	Patients showing >50–75% of relief in symptoms.
3.	Partially improved	Patients showing 25–50% of relief in symptoms.
4.	Unimproved	Patients showing >25% of relief in symptoms.

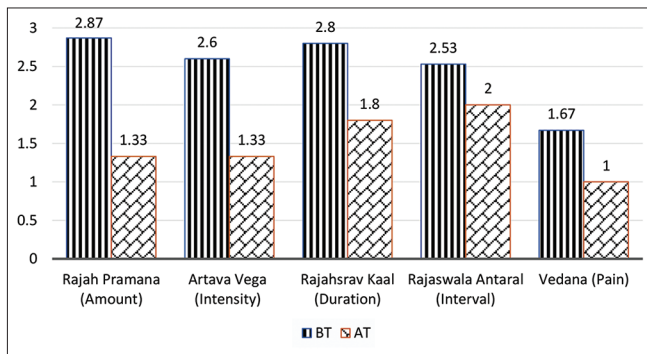
Bar Diagram No. 1

**Chart 1:** Overall effect of therapy in Group I (Oral+Basti) on subjective criteria

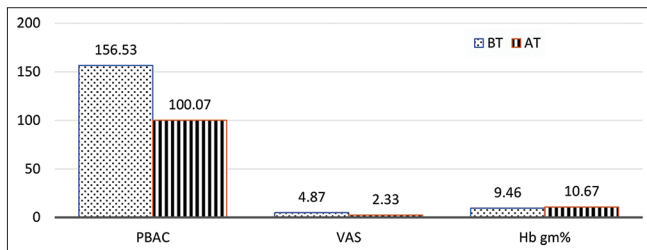
Bar Diagram No. 2

**Chart 2:** Effect of therapy on objective criteria of group I (Oral+Basti)

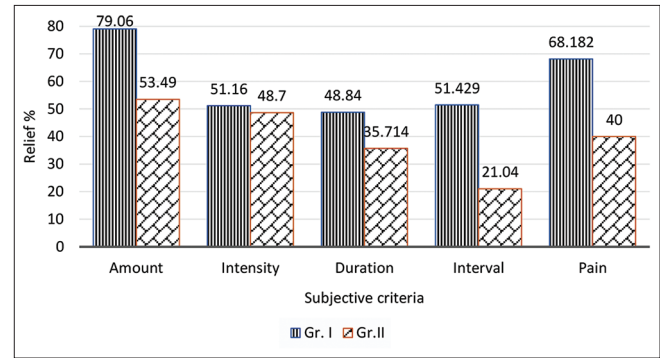
Bar Diagram No.3

**Chart 3:** Effect of therapy on subjective criteria of Group-II (without Basti)

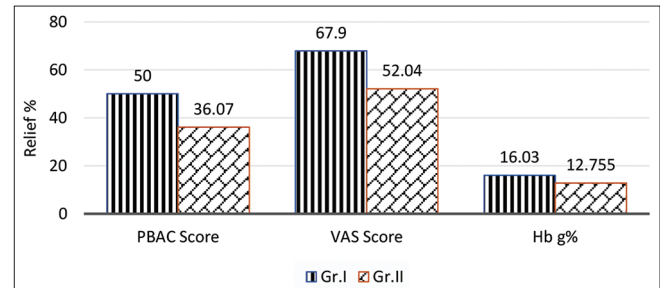
Bar Diagram No.4

**Chart 4:** Effect of therapy on objective criteria of Group-II (without Basti)

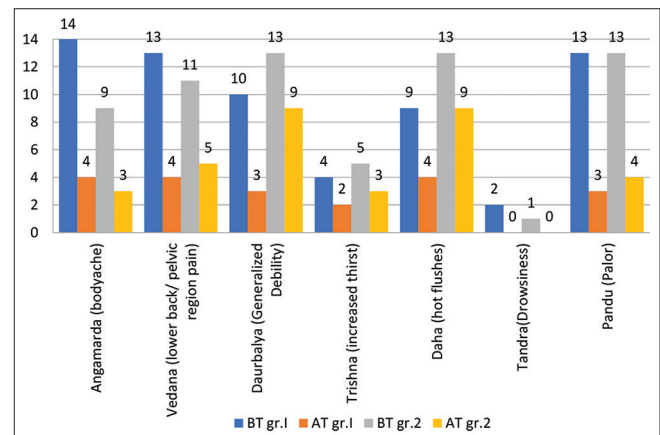
Bar Diagram No. 5

**Chart 5:** Intergroup comparison over subjective criteria of assessment

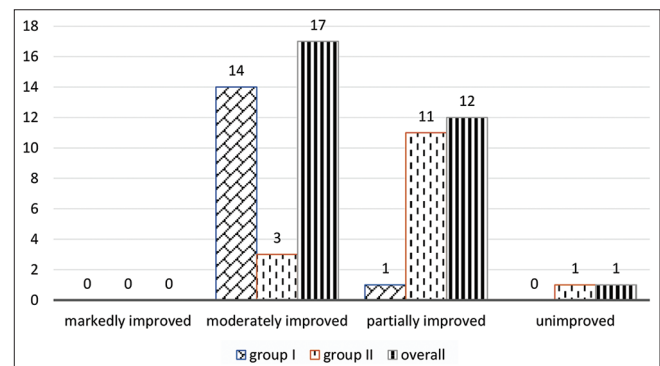
Bar Diagram No.6

**Chart 6:** Intergroup comparison of effect of therapy on objective assessment criteria

Bar Diagram No.7

**Chart 7:** Overall effects on incidence of associated features

Bar Diagram No.8

**Chart 8:** Overall improvement in all patients

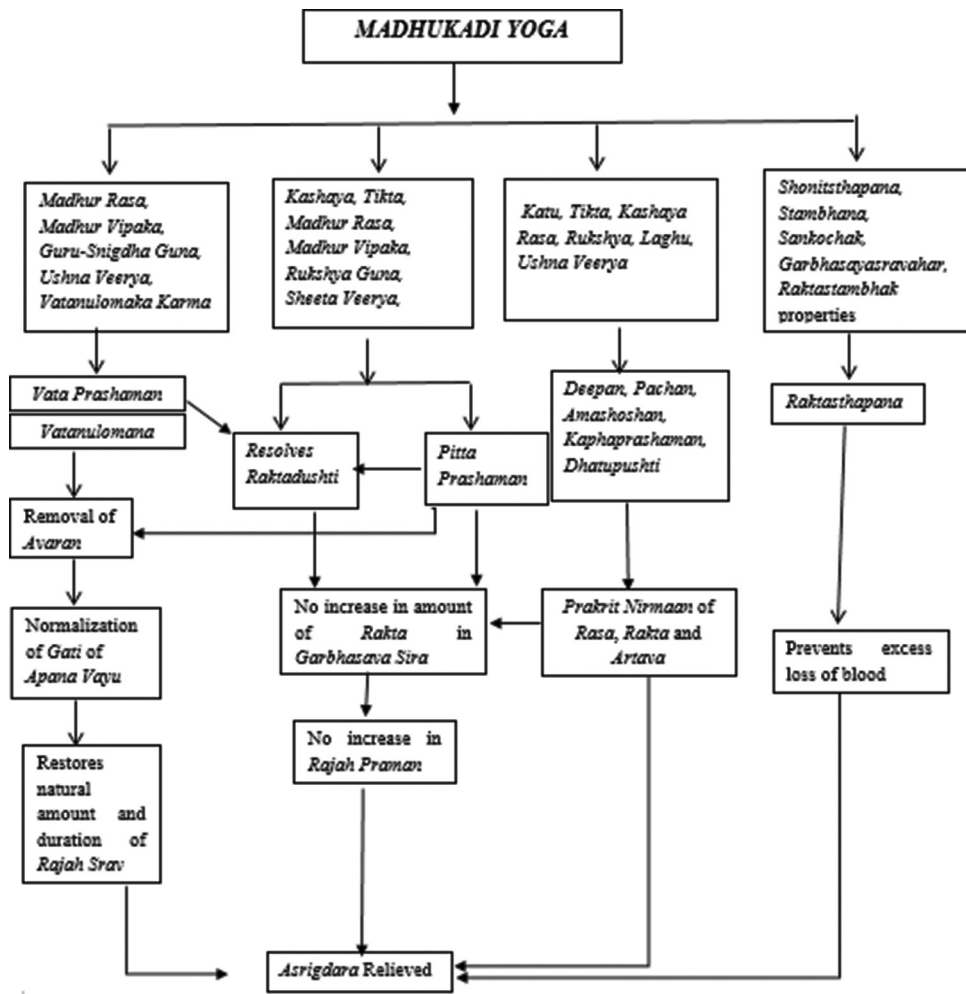


Figure 1: Schematic diagram showing probable mode of action of Madhukadi Yoga

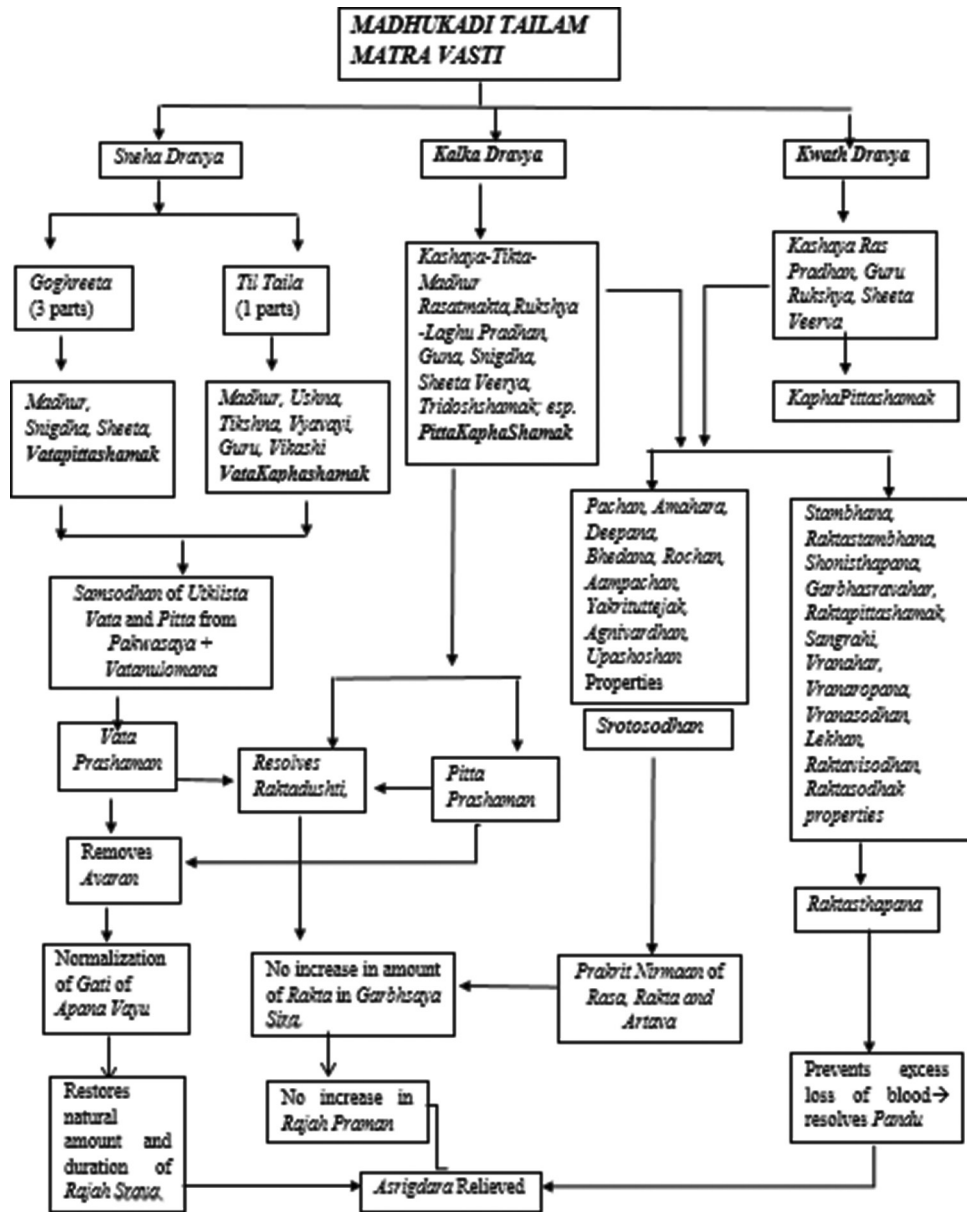


Figure 2: Schematic diagram showing probable mode of action of Madhukadi Tailam Matra Basti

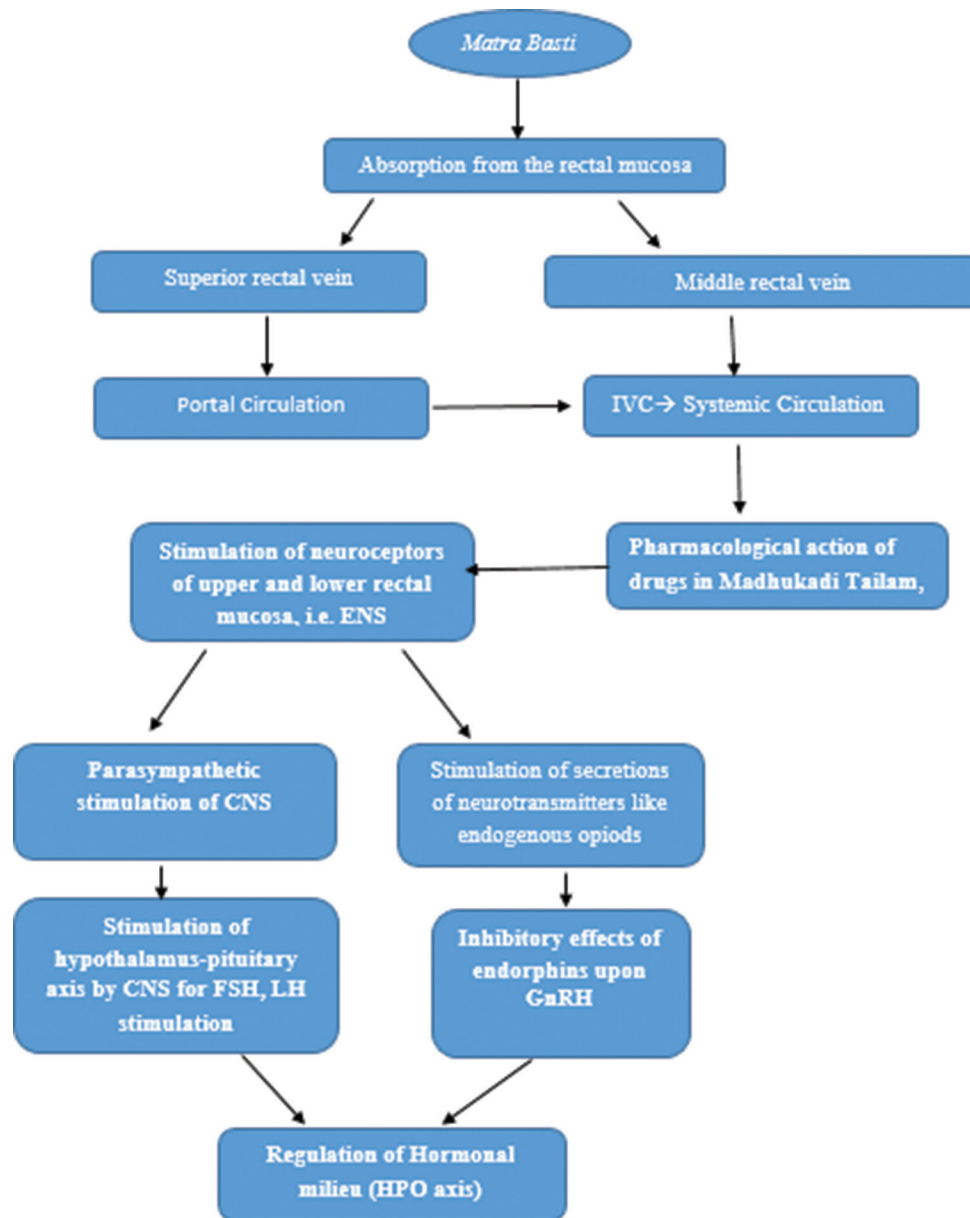


Figure 3: Probable mode of action of Basti

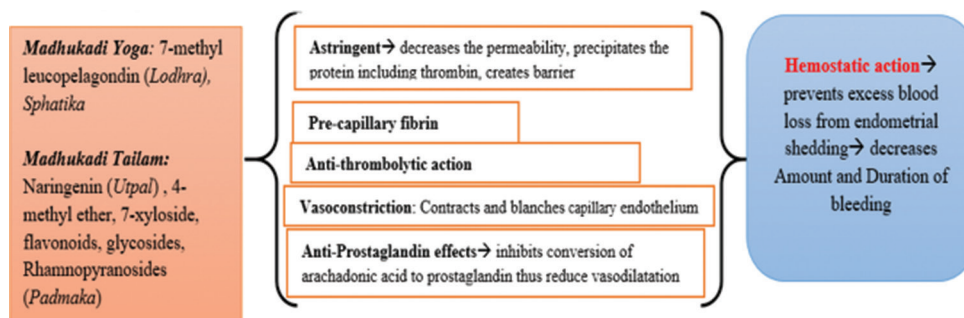


Figure 4: Anti-hemorrhagic constituents

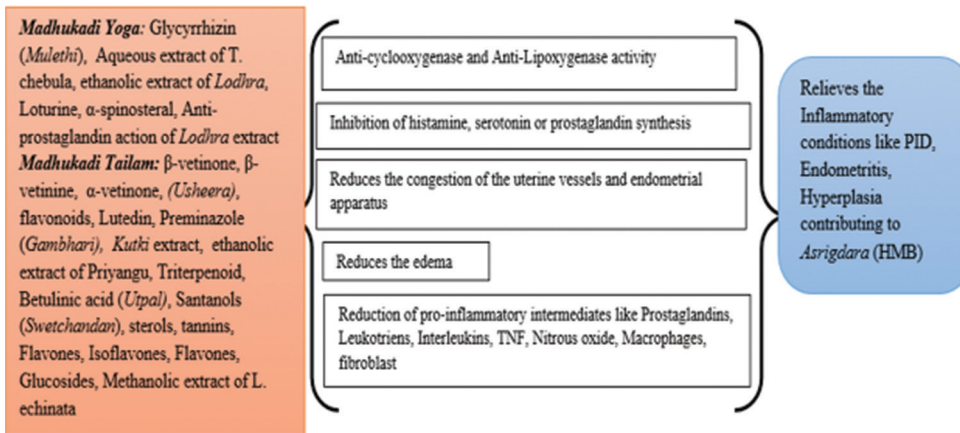


Figure 5: Anti-inflammatory constituents

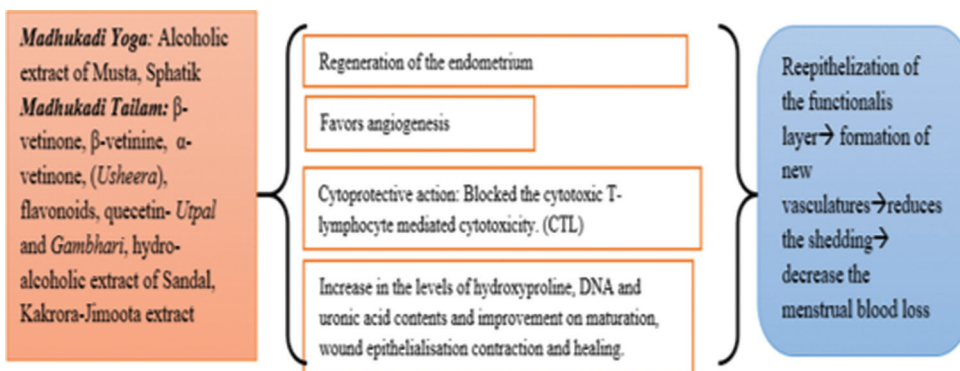


Figure 6: Wound healing constituents

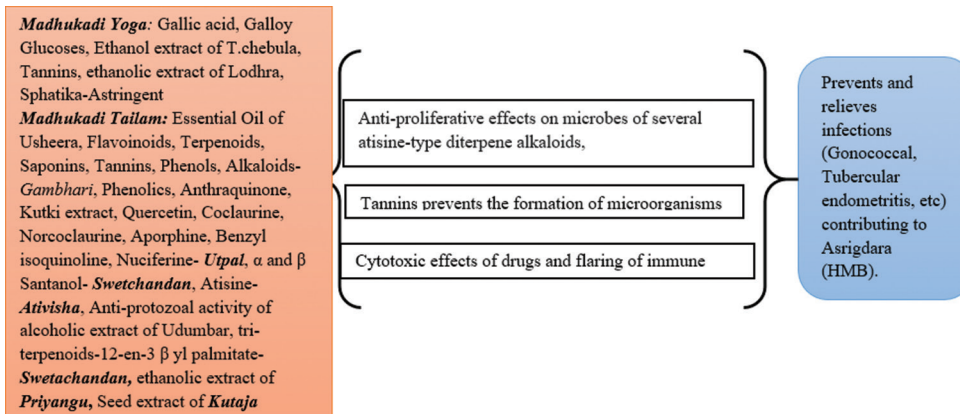


Figure 7: Anti-microbial constituents

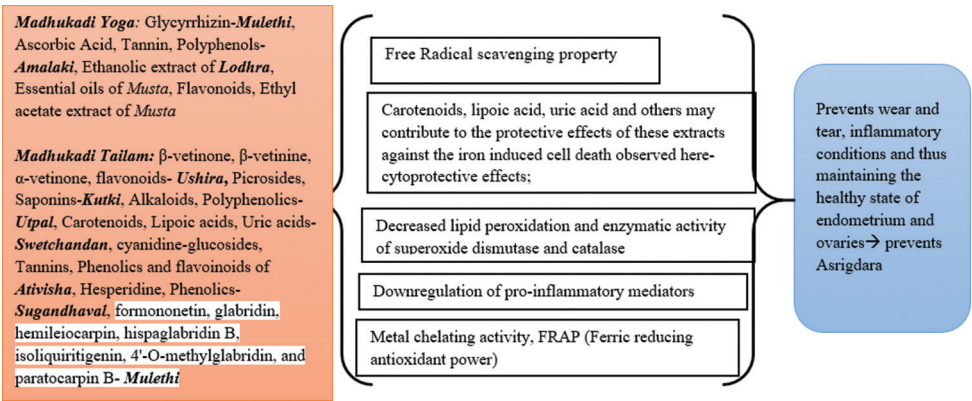


Figure 8: Anti-oxidant constituents

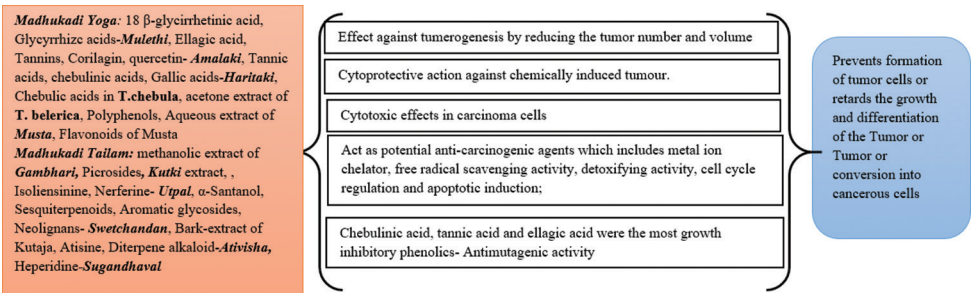


Figure 9: Anti-tumor constituents

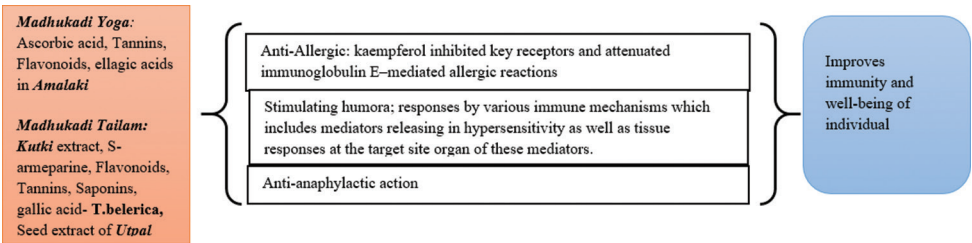


Figure 10: Immunomodulatory constituents