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A RANDOMIZED CONTROLLED STUDY OF *BHUMYAMALAKI MULA CHURNA* AND *YASTIMADHU CHURNA* IN THE MANAGEMENT OF *RAKTAPRADARA (DUB)*

SHRIRAKSHA GAIKWAD K.G[1] SHREYES. S[2] YOGITHA BALI M.R[3*]

[1]PG Scholar, [2]Associate Professor, Department of PG Studies in Prasuti Tantra and Stree Roga, Rajiv Gandhi Education Society's Ayurvedic Medical College and Hospital, Ron, Karnataka

[3*]Professor, Department of Shareera Rachana, Sushrutha Ayurvedic Medical College and Hospital, Bangalore, Karnataka

Corresponding Author Email: shrss02@gmail.com Access this article online: www.jahm.co.in

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ABSTRACT:

Background: Dysfunctional uterine bleeding that can be correlated in Ayurveda as Rakta Pradara is the common problem most suffered and came across by Gynaecologist in current practice. It's more prevalent and growing higher due to modernization and change in our daily dietary habits and physical activities. Design: This was a randomized controlled comparative clinical study including 40 patients in two groups, Group A and Group B with 20 patients each with before and after assessment. Intervention: Group A received *Bhumyamalaki Mula Churna (Powder of Phyllanthus niruri)* 3gms with *Tandulodaka Anupana (Adjuvant)* before food, thrice a day for 30 days from 5th day of the menstrual cycle in 3 cycles. Group B received *Yastimadhu Churna (Powder of Glycyrrhiza Glabra)* 3gms with *Sita* and *Tandulodaka (Rice water)* as *Anupana (Adjuvant)* before food, thrice a day for 30 days from 5th day of the menstrual cycle in 3 cycles. **Results:** Both between and within groups with repeated measures analysis of variance (RMANOVA), Bonferroni showed significant changes in Group A *(Bhumyamalaki Mula Churna)* compared to Group B *(Yastimadhu Churna)* with ($p \leq 0.05$). **Conclusion:** *Bhumyamalaki Mula Churna* is effective compared to *Yastimadhu Churna* in patients suffering from Rakta pradara.

Keywords: Raktapradara, DUB, Ayurveda, Bhumyamalaki Mula Churna, Yastimadhu Churna

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INTRODUCTION

Gynaecological morbidities are said to influence the women in all aspects of health including physical health, social health, sexual health, psychological status and religious life. [1] In India, research studies have shown a high rise of these gynaecological morbidities and a specific community reported that overall, 20.28% of the women had either one or more gynaecological disorders. [2] The incidence of dysfunctional uterine bleeding is estimated to be around 3%-30% worldwide. [3] Among the affected, 25% of women were in their reproductive ages. [4] It is also observed that nearly 80% of patients with menorrhagia present with underlying cause as dysfunctional endometrial bleeding. [5]

Any abnormal bleeding from uterus in the absence of an organic pathology is defined as Dysfunctional uterine bleeding (DUB). It is commonly observed in reproductive and perimenopausal age groups. It is also defined as excessive, heavy or prolonged uterine bleeding with >80ml per month and the absence of systemic or genital tract pathology. [6] In Ayurveda, DUB is correlated to *Rakta Pradara* and is described as a *Rakta Pradoshaja Vikara (Disease related to blood)* which is mainly caused due to *Vata Pitta Dosha*. Any deviation in regularity and quantity of the *Rutuchakra* or the menstrual cycle is also termed as *Rakta Pradara*. It presents with features such as *Deergha Kala Pravrutti (Poly- menorrhagia), Anruta Kala Pravrutti (Inter-menstrual bleeding)*, *Artava Ati Pravrutti (Polymenorrhoea), Daha* in *Adho Vankshana Pradesha, Sroni (Burning sensation in lower abdomen and pelvic area), Prushta* and *Kukshi Shoola* in *Garbhashaya (Abdominal pain or Pelvic pain) Angamardha (Malaise)* etc. Regarding management, *Vatapitta Shamaka* treatments are adopted with *Kashaya Rasa (Astringent taste)* and *Pittashamaka Chikitsa (Treatment that alleviates pitta dosha)* too. [3]

According to the Modern science, DUB is treated with nonsteroidal anti-inflammatory drugs or tranexamic acid with danazol and GnRH analogues etc. Hysterectomy is advised in case of severe bleeding and when it affects woman's quality of life with no plan of conception in future. [7] With the knowledge of the adverse effects and the fear of surgeries, many patients resort to Ayurveda treatment to relieve the problem, correct the hormonal imbalance of the reproductive system and also to obtain overall positive health and well-being.

OBJECTIVES OF THE STUDY

Objectives of the present study was to evaluate the clinical efficacy of Bhumyamalaki

mula churna and Yastimadhu Churna in the management of Rakta Pradara w.s.r to Dysfunctional Uterine Bleeding - A comparative study.

MATERIALS AND METHODS

This was a randomized comparative clinical study and randomization was done using a computer-generated random number table on the www. randomizer.org software. Sample size was derived by calculating the effect size based on the mean and standard deviation (SD) of an earlier clinical study conducted on the *Raktapradara* and Ayurvedic intervention. Female patients with the features of *Rakta Pradara* were recruited from the outpatient and in-patient Department of *Prasooti Tantra Evam Stree Roga* at R.G.E.S Ayurvedic Medical College and hospital Ron. After the initial screening, patients who fulfilled the eligible criteria were assigned into the groups with 40 patients divided in two groups, Group A and Group B with 20 patients each. (Figure No.1 Flowchart) The study was approved by the IRB of Institutional Ethical committee of R.G.E.S Ayurvedic Medical College and hospital Ron. Signed informed consent was obtained from all the patients. The statistician and the researcher who carried out the assessments were blinded to the treatment status of the patients. Statistical analysis was done using appropriate statistical methods and results were interpreted.

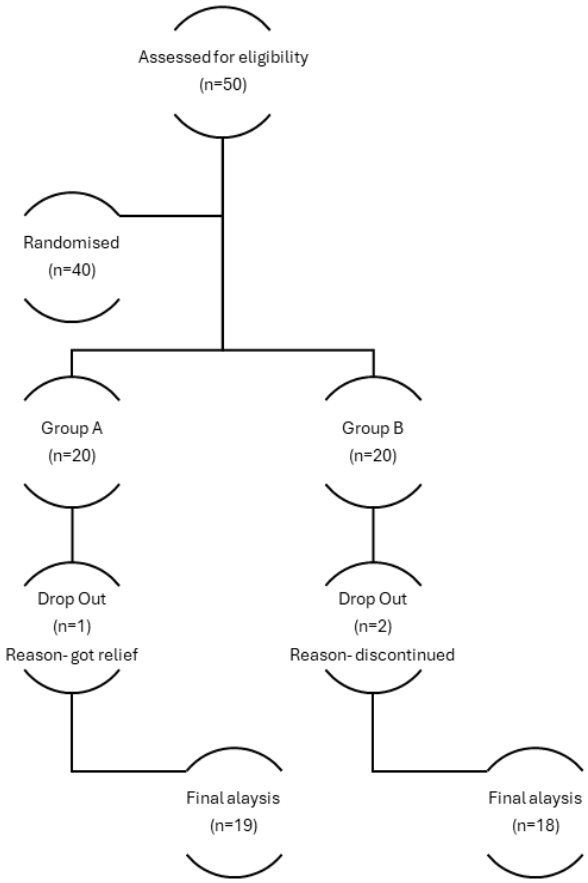

Figure No.1 CONSORT Flowchart

Inclusion criteria

Female patients between the age groups of 20 – 40 years, Patients with the *Lakshanas (Symptoms)* of *Rakta Pradar*a, Patients with complaints of excess of bleeding per vagina. Altered menstrual cycle and Patients diagnosed as dysfunctional uterine bleeding.

Exclusion criteria

Patients with Thyroid dysfunction, DM, HTN. Patients with threatened or spontaneous or incomplete abortion or Ectopic pregnancy. Patients with IUCD, Polyp, Benign and Malignant. Bleeding diathesis like

thrombocytopenia etc., Ovarian benign and malignant tumour. CA Cervix. Uterine polyps, other any pelvic inflammatory diseases. Patient with IUD. Sexually Transmitted Diseases were excluded from the study.

Intervention

Table No.1 Intervention

Sl.No	Group A	Group B
Drug	*Bhumyamalaki Mula Churna*	*Yastimadhu Churna*
Anupana	*Tandulodaka*	*Sita* and *Tandulodaka*
Dose	3gms	3gms
Time of Administration	Thrice a day1	Thrice a day
Duration	30 days in 3 cycles	30 days in 3 cycles
Follow up	120th day	120th day

Group A received *Bhumyamalaki Mula Churna* and Group B *Yastimadhu Churna* on 5th day of the menstrual cycle for 30 days in 3 cycles. (Table No.2) *Bhumyamalaki Mula Churna* mentioned by Acharya *Yogarathnakara* and *Yastimadhu Churna* mentioned by Acharya *Bhavaprakasha* for the management of *Raktapradara* has been selected for the present study. The drug *Bhumyamalaki Mula* and *Yastimadhu* was collected and churna was prepared in the Department of *Dravyaguna (Branch of Ayurvedic medicine),* RGES Ayurvedic Medical College and hospital, Ron.

Outcomes

Subjective Parameters

1. Pain

Objective Parameters (Menstrual Bleeding)

1. Duration of the Menstrual flow
2. Interval between the Menstrual cycle
3. Amount of Menstrual bleeding loss
4. Consistency of bleeding
5. Staining
6. Intensity of pain during menstruation
7. Colour of menstrual bleeding

All the symptoms were graded before, during and after the treatment. Assessments were be carried out before the treatment on the 1st day, 30th day, during the treatment and 60th day after the treatment. (Table No.2)

Table no. 2 Assessment scale

Sl.No			Grading
1.	Duration of the Menstrual flow	1 - 5 days	0

		6 - 7 days	1
		8- 9 days	2
		> 10 days	3
2.	Interval between the Menstrual cycle		
	Normal	28 to 32 days	0
	Frequent	Menstrual bleeding occurring at 21 days cycle or less	1
	Inter Menstrual	Menstrual bleeding occurring at 15 to 16 days cycle	2
	Delayed	Menstrual bleeding occurring > 35 days	3
3.	Amount of Menstrual bleeding loss	1 to 3 Pads/day	0
		4 to 6 Pads/day	1
		to 9 Pads/day	2
4.	Consistency of Bleeding	Watery	1
		Watery + clots	2
		Clots (mild)	3
		Clots (moderate)	4
		Clots (severe)	5
5.	Staining	Present	1
		Absent	0
6.	Intensity of pain during menstruation	Absent	0
		Mild	1
		Moderate	2
		Severe	3
7.	Colour of menstrual bleeding	Absent	0
		Light red	1
		Dark red	2
		Blackish colour	3

RESULTS

There was 1 drop out in group A and 2 in the group B and the analysis was carried out on 37 patients. In this study maximum number of 31(77.5%) patients were traced from the age group of 26-35 years, 29(72.5%) patients were belonging to Hindu community, 22(55%) patients had their high school education

followed by 11(27.5%) receiving primary education and only 7(17.5%) were graduated, 25(62.5%) patients belonged to lower middle class and 9(22.5%) were from lower class and middle class were 6 (15%). Non-working women include 25(62.5%) and 19(47.5%) patients had their menarche at the age of 13 years. Between the groups, repeated measures analysis of variance (RMANOVA) with Bonferroni showed significant changes in Group A *(Bhumyamalaki Mula Churna)* showed significant changes compared to Group B *(Yastimadhu Churna)* with all the parameters with ($p \leq 0.05$). (Table 3)

Within the group, Group A *(Bhumyamalaki Mula Churna)* showed reduction in pain on 30^{th} day (7.5±0.5), 60^{th} day (3.6±0.8), 90^{th} day (0.7±0.5) and on 120^{th} day (0±0). Duration of the menstrual flow on 30^{th} day (1.4±0.5), 60^{th} day (0.6±0.5), 90^{th} day (0.2±0.4) and on 120^{th} day (0±0). Interval between the menstrual cycle on 30^{th} day (1.8±0.4), 60^{th} day (0.8±0.5), 90^{th} day (0.1±0.3) and on 120^{th} day (0.3±0.5). Amount of Menstrual bleeding loss on 30^{th} day (1.2±0.4), 60^{th} day (0.8±0.4), 90^{th} day (0.2±0.4) and on 120^{th} day (0±0). Consistency of bleeding on 30^{th} day (2.9±0.5), 60^{th} day (1.7±0.6), 90^{th} day (1.1±0.2) and on 120^{th} day (1±0). Staining on 30^{th} day (1±0), 60^{th} day (0±0), 90^{th} day (0±0) and on 120^{th} day (0.1±0.24). Intensity of pain during menstruation on 30^{th} day (2.3±0.5), 60^{th} day (1.3±0.7), 90^{th} day (0.5±0.5) and on 120^{th} day (0±0) and colour of menstrual bleeding on 30^{th} day (1.8±0.4), 60^{th} day (0.7±0.5), 90^{th} day (0±0) and on 120^{th} day (0±0).

Group B *(Yastimadhu Churna)* also showed reduction in pain on 30^{th} day (8.8±0.8), 60^{th} day (6.4±0.9), 90^{th} day (3.6±0.9) and on 120^{th} day (1.9±0.7) compared to before treatment ($p \leq 0.05$). Duration of the menstrual flow on 30^{th} day (2.5±0.5), 60^{th} day (2.2±0.5), 90^{th} day (1.9±0.5) and on 120^{th} day (1.3±0.5) compared to before treatment ($p \leq 0.05$). Interval between the menstrual cycle on 30^{th} day (2.5±0.5), 60^{th} day (2±0), 90^{th} day (1.9±0.3) and on 120^{th} day (1.4±0.6) compared to before treatment ($p \leq 0.05$). Amount of Menstrual bleeding loss on 30^{th} day (2±0), 60^{th} day (1.6±0.5), 90^{th} day (1.5±0.5) and on 120^{th} day (1±0.5) compared to before treatment ($p \leq 0.05$). Consistency of bleeding on 30^{th} day (3.8±0.4), 60^{th} day (3.8±0.4), 90^{th} day (2.9±0.5) and on 120^{th} day (2.5±0.6) compared to before treatment ($p \leq 0.05$). Staining on 30^{th} day (1±0), 60^{th} day (1±0), 90^{th} day (0.8±0.4) and on 120^{th} day (0.7±0.5) compared to before treatment ($p \leq 0.05$). Intensity of pain during menstruation on 30^{th} day (3±0), 60^{th} day (2.6±0.5), 90^{th} day (1.9±0.6) and on 120^{th} day (1.5±0.5) compared to before treatment ($p \leq 0.05$). colour of menstrual bleeding on 30^{th} day (2.9±0.2), 60^{th}

day (2.4±0.5), 90th day (1.9±0.2) and on 120th day (1.5±0.5) compared to before treatment (p≤0.05).

Table No.3 Results Between and Within Groups

	Group A					Group B					
	BT	30th D	60th D	90th D	120th D (FU)	BT	30th D	60th D	90th D	120th D (FU)	p value
	(Mean±SD)	(Mean±SD)	(Mean±SD)	(Mean±SD)	(Mean±SD)	(Mean±SD)	(Mean±SD)	(Mean±SD)	(Mean±SD)	(Mean±SD)	
VAS	10±0	7.5±0.5	3.6±0.8	0.7±0.5	0±0	10±0	8.8±0.8	6.4±0.9	3.6±0.9	1.9±0.7	p≤0.05
DMF	3±0	1.4±0.5	0.6±0.5	0.2±0.4	0±0	3±0	2.5±0.5	2.2±0.5	1.9±0.5	1.3±0.5	p≤0.05
IMC	3±0	1.8±0.4	0.8±0.5	0.1±0.3	0.3±0.5	3±0	2.5±0.5	2±0	1.9±0.3	1.4±0.6	p≤0.05
A	2±0	1.2±0.4	0.8±0.4	0.2±0.4	0±0	2±0	2±0	1.6±0.5	1.5±0.5	1±0.5	p≤0.05
C	5±0	2.9±0.5	1.7±0.6	1.1±0.2	1±0	5±0	3.8±0.4	3.8±0.4	2.9±0.5	2.5±0.6	p≤0.05
S	1±0	1±0	0±0	0±0	0.1±0.24	1±0	1±0	1±0	0.8±0.4	0.7±0.5	p≤0.05
IOP	3±0	2.3±0.5	1.3±0.7	0.5±0.5	0±0	3±0	3±0	2.6±0.5	1.9±0.6	1.5±0.5	p≤0.05
CL	3±0	1.8±0.4	0.7±0.5	0±0	0±0	3±0	2.9±0.2	2.4±0.5	1.9±0.2	1.5±0.5	p≤0.05

Footnote: BT-Before Treatment, AT- After Treatment, D-Day, VAS- Visual analogue scale, DMF-Duration of menstrual flow, IMC-Interval between the menstrual cycle, A- Amount, C-Consistency, S-Staining, IOP-Intensity of pain during menstruation, CL-Colour

DISCUSSION

Ayurvedic medicine is gaining momentum due to its betterment towards human health in

perspectives of safety, stability, efficacy and quality and these are used in the form of both raw and crude materials, extracts and also in the preparation of medicines for therapeutic purposes. [8] According to the conventional guidelines, in normal menstruation, duration of menstrual blood flow is 2-7 days with cycle length of 21-35 days and blood loss is 20-80ml. Any deviation from this normal pattern is recognized as abnormal. [9] Any abnormal uterine bleeding that affects women is described as Dysfunctional uterine bleeding (DUB with unclear aetiology. DUB presents in three forms as primary, secondary and iatrogenic groups. Primary DUB is caused due to dysfunction of the hypothalamo-pituitary-ovarian axis or dysfunction in the endometrium itself. Secondary DUB is due to haematological, vascular disease, endocrinopathies and liver disorders. Iatrogenic DUB is the one that has caused by drugs, exogenous hormone administration and intrauterine contraceptive devices. [10]

International Federation of Gynaecology and Obstetrics (FIGO) has given the definition for abnormal uterine bleeding in 2007. [11] The PALM-COEIN acronym is now being widely used for categorizing the causes of AUB such as adenomyosis (AUB-A), leiomyoma (AUB-L), malignancy and hyperplasia (AUB-M), coagulopathy (AUB-C) etc. [12] Conventional management of DUB includes include nonsteroidal anti-inflammatory drugs, oral contraceptive pills, progestins, danazol (a synthetic androgen), GnRH agonists, and antifibrinolytic drugs. Though this medical therapy is very effective in reduction of the problem, it is associated with multiple adverse effects. Surgical treatment concentrates mainly on the endometrial ablation and there are newer and less invasive ablation techniques, such as thermal balloon ablation that offer as alternatives and are still under the experimentation. [13]

Different authors have opined differently regarding the disease with respect to its aetiology, symptoms and treatment etc. Acharya Charaka explained *Pradara (Vaginal Discharge)* under *Yoni Vyapad Chikista (Gynaecological disorders)* and as a separate disease with its management. Whereas Acharya *Sushruta (Father of Ayurvedic Surgery)* explained it in *Sharirasthana (One Section of Book of Sushrutha Samhitha)* under *Shrukra Shonita Adhyaya (One Chapter of Book of Sushrutha Samhitha)*. In *Ashtanga Sangraha*, *Raktapradara* has been explained as Asrigdara. In addition, various treatments have been mentioned by *Acharyas (Teacher)* for the effective management of *Raktapradara* or DUB.

Between the groups, Repeated measures analysis of variance (RMANOVA) with Bonferroni showed significant changes in Group A *(Bhumyamalaki Mula Churna)* showed significant changes compared to Group B *(Yastimadhu Churna)* with all the parameters with (p≤0.05). Within the groups all the parameters such as pain, duration of the menstrual flow, Interval between the Menstrual cycle, Amount of Menstrual bleeding loss, Consistency of bleeding, Staining, Intensity of pain during menstruation and Colour of menstrual bleeding showed significant changes in both the groups Group A *(Bhumyamalaki Mula Churna)* and Group B *(Yastimadhu churna)* after the treatment compared to before treatment with (p≤0.05).

The intervention used in the study both *Bhumyamalaki and Yastimadhu Churna* have shown its effectiveness in *Raktapradara* in reducing all the parameters. *Bhumyamalaki* is endowed with properties such as *Madhura (Sweet taste), Tikta (Bitter taste)* and *Kasaya Rasa (Astringent taste), Laghu-Ruksha Guna (Lightness-Dryness), Sheetaveerya (Cold in potency), Madhura Vipaka (Sweet taste after digestion)* and is *Kapha-Pitta Shamaka (Alleviation of Kapha and Pitta doshas) , Raktapitta Shamaka (Alleviation of Rakta and Pitta doshas)* and has *Yonidoshahara (Alleviation of Vaginal disorders)* properties. It also has anti-inflammatory and analgesic properties that influences the vascular apparatus of reproductive system. In addition, it also does *Kleda Shoshana (Dryness of moisture), Raktapitta Prashamana (Alleviation of Rakta and Pitta doshas), Lekhana (Scraping), Samgrahi (Absorbs moisture) and Stambhaka (Stoppage or blockage of body fluids)*. This Lekhana action of *Bhumyamalaki* helps in the scraping of endometrium thereby reducing the endometrial thickness that resembles with “medical curettage”. With its *Shothahara (Anti-inflammatory)* properties it reduces uterine congestion also by its *Shothahara (Anti-inflammatory)* action. It also has *Dahaprashamana (Reduction of burning sensation)* action and corrects burning sensation of the body. [14] *Yastimadhu,* according to Ayurveda, has *Madhura Rasa (Sweet taste), Guru (Heaviness) and Snigdha Guna (Unctuousness), Sheeta Veerya (Cold in potency)* and *Madhura Vipaka (Sweet taste after digestion).* It has *Vatapittashamana (Alleviation of Vata and pitta doshas), Dahashamana (Reduces burning sensation), Keshya (Helps in hair growth), Vedanasthapana (Analgesic), Shothahara (Anti-inflammatory), Vatanulomana (Downward movement of Vata dosha)* and *Mridurechana (Mild purgative)* etc properties. It acts as depressive, antiulcer, liver protective,

estrogenic, emmenagogue and antidiabetic. Some other actions like anti-microbial, hypolipidemic, antiatherosclerosis, demulcent, expectorant, antiallergic, anti-inflammatory, spasmolytic, mild laxative, antistress antiviral, hypotensive, anti-exudative, antidiuretic, antimutagenic, antipyretic, antioxidant and anti-nociceptive have also been reported. [15] *Tandulodaka (Rice washed water)* administered as the adjuvant with these *Churnas (Powders)* becomes more effective in reducing the problem with its *Madhura Rasa, Laghu, Snigdhaguna, Sheeta Veerya, Madhura Vipaka and Pitta Shamaka. Balya (One that provides strength), Doshaghna (Alleviating doshas), Sukrala (Increases semen), Mutrala (corrects urinary disorders), Chakshusya(Improves eyesight),Varnya(Improves complexion), Swarya(Improves voice), Hridya (Good for heart), Jwaraghna (Anti-pyrexia),Trishnaghna (Reduces thirst), Sarvadoshavishahara (Best for alleviation of doshas poisons)* etc properties. It possesses anti-inflammatory, anti-fungal properties and antioxidant actions and helps in eliminating the chronic infection of uterus and pelvic congestion thus reducing the loss of menstrual blood. Presence of Vitamin B complex in *Tandulodaka (Rice washed water)* may help in normalizing the oestrogen metabolism and with its endothelial activity of the arteries bleeding reduces. [14]

Limitations of the study

Sample size was small, Patients were not comfortable with consumption of medicine in the *Churna (Powder)* form, Palatability of *Tandulodaka (Rice washed water)* was not accepted and patients preferred normal water instead, Collection of *Bhumyamalaki Mula Churna (powder of root)* was very difficult and yield of *Bhumyamalaki Mula Churna* was less.

Strengths of the study

Patients were happy due to early relief and effectiveness, Patients were able to get back to their life fast, their quality of life was improved and both the *Churnas (Powder)* were very effective in reduction of the complaints.

Future recommendations of the study

Larger sample size, *Churna (Powder)* consumption in the Vati (Tablet) form would be comfortable to the patients, awareness on Importance and Palatability of *Tandulodaka (Rice washed water)* is needed before the administration of the Medicine and a longer Follow up would be recommended.

CONCLUSION

DUB or *Raktapradara* is one among these disorders that affect women to a larger extent and the present randomized controlled comparative clinical study evaluates an

Ayurvedic intervention in the management of *Raktapradara* including 40 patients categorized into two groups as Group A and Group B with 20 patients each. Between groups with repeated measures analysis of variance (RMANOVA) with Bonferroni showed significant changes in Group A *(Bhumyamalaki Mula Churna)* compared to Group B *(Yastimadhu Churna)* on all the parameters with ($p \leq 0.05$). Within group results with repeated measures analysis of variance (RMANOVA) with Bonferroni also showed significant changes in Group A *(Bhumyamalaki Mula Churna)* and Group B *(Yashtimadhu Churna)* on pain, duration of the menstrual flow, Interval between the Menstrual cycle, Amount of Menstrual bleeding loss, Consistency of bleeding, Staining, Intensity of pain during menstruation and Colour of menstrual bleeding with ($p \leq 0.05$) after the treatment compared to before the treatment. The present research shows that the *Bhumyamalaki Mula Churna* is more effective compared to *Yastimadhu Churna* in patients suffering from *Rakta Pradara (DUB)*.

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Conflicts of Interest: Nil

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