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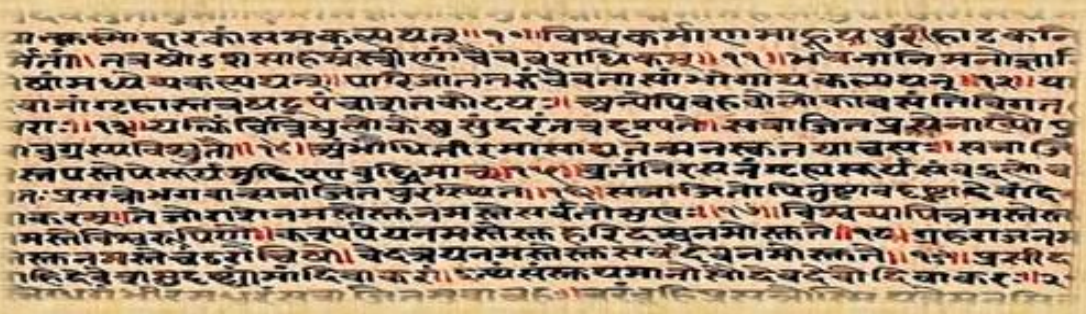

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"A RANDOMIZED CLINICAL TRIAL TO EVALUATE THE EFFECT OF JAMBU BEEJ CHURNA IN AND NAGKESHAR CHURNA IN TREATING RAKTAPRADARA."

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ABSTRACT:

Background: The word Artava denotes two meanings one of them is 'Antah Pushpa' i.e., ovum and another one is 'Bahir Pushpa' Menstrual flow (Rajastrava). Both Antah and Bahir Pushpa are interrelated. Bahir Pushpa is outward manifestation of appropriate work of Antah Pushpa which is necessary for conception. Aim & Objective: To evaluate the effect of Jambu beej churna and Nagkeshar churna in treating Raktapradara. To achive reduction in duration and quantity of per vaginal bleeding in Raktapradara. Methods: Female patients complaining mainly of Raktapradar were selected irrespective of Age, Sex, occupation, religion, and prakruti. Total duration of the Treatment is for 03 successive menstrual cycles. Thus, Observations and Investigations necessary would be carried on the 1st, 3rd, 7th, 10th, 15th day of first menstrual cycle and then on 5th day of next 2 menstrual. Results & Conclusion: It can be concluded that Jambu beej Churna (Trial drug) is quite effective on Raktapradar. Nagkeshar churna (Control drug) is found efficacious in comparison with Jambu beej Churna in Raktapradar disease. Nagkeshar Churna shows better Statistical results than the Trial drug.

KEYWORDS: Raktapradar,Nagkeshar churna, Jambu beej churna

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The health of Nation mainly depends on the health of woman because the healthy and happy woman lays the first step of aprosperous nation. Any feeling of physical or psychological factor directly affects her attitude and efficacy which adversely affects the family. Ayurveda has given principal significance to women health it has mentioned menstrual cycle as "Rutuchakra" and menses is phrased as "Rajastrava". Impressive explanation of "Shuddha Raja" (Normal menstrual flow) has been imposed by our Acharya's. The word Artava denotes two meanings one of them is 'Antah Pushpa' i.e., ovum and another one is 'Bahir Pushpa' Menstrual flow (Rajastrava). Both Antah and Bahir Pushpa are interrelated. Bahir Pushpa is an outward manifestation of appropriate work of Antah Pushpa which is necessary for conception. Here, the present study deals with Bahir Pushpa that is menstrual blood. Menstruation is a natural physical specific property of a female and so, it called as monthly period.Artava or Mentrual blood is expelled from the uterus through vagina in biological rhythm of women during her reproductive period i.e. from menarche to menopause. During daily medical practice we often come across different gynecological complaints e.g- Yonigat shwet strav, Yoni kandu, Yoni dah etc. Among which"Raktapradar" is much common, it affects the whole efficacy of woman. Maharashi Charka have described that treatment of Raktapradara is similar to that of Raktatisara, Raktapitta and Raktarsha various herbs, herbal compounds, metallic compounds and medical regimens are prescribed in the management of above conditions as haemostatic or Raktastambhaka attributes should be employed in Raktapradara. If Raktapradar is untreated it can lead to major suffering for the women and can hamper her day-to-day activities more over it can cause severe anaemia which can further debilitate the patient hence prompt and effective treatment is required in Raktapradara. Due to limitation of medical therapy as well surgical therapy of modern science, it becomes the necessity of the time to find out an efficational harmless therapy to manage the condition. As Jambu beej churna are easy to available or easy to prepare, they are also coast effective and easy to consume also. Jambu Beej churna is used as haemostatic and in various vaginal condtions Nagkeshara is also one of trusted drug used in various bleeding conditions.

AIM & OBJECTIVES

AIM: -

- To evaluate the effect of Jambu beej churna in treating Raktapradara.
- To evaluate the effect of Nagkeshar churna in treating Raktapradara.
- To compare the effect of Nagkeshar churna and Jambu beej churna in treating Raktapradara.
- **OBJECTIVE:**
- To study literature of Raktapradara as per principal texts of Ayurveda and Modern text. To find out lacuna in the knowledge in subject concerned in present context.
- To study the efficacy of Jambu Beej Churna & Nagkeshar churna in the management of Raktapradara.
- Duration and quantity of per vaginal bleeding will be measured during and after study.
- To achive reduction in duration and quantity of per vaginal bleeding in Raktapradara.
- Jambu Beej Churna will be given to patient from 1st day of menstrual cycle for 15 days and follow up will be taken for next three cycles.

Methodology:

MATERIAL AND METHODS-

Selection of Patients: -

Female patients complaining mainly of Raktapradar were selected irrespective

of Age, Sex, occupation, religion, and prakruti.

CLINICAL STUDY: -

A) Study Design: - Randomized clinical trial

B) Inclusion Criteria: -

- Patient from age group 19 - 45 yrs old.
- Patient having excessive menstrual bleeding during menstrual cycle or intermenstrual period in the form of quantity and duration with or without associated symptoms with minimum of 3 months i)
- Hb above 7 gm %

C) Exclusion Criteria: -

- Any palpable pathology (tumour, fibroid, polyp, cyst, abnormal mass etc) ii)
- Patients who have taken IUCD & OC pills or on hormonal treatment.
- Bleeding disorder other than Raktapradara.
- Known cases of menopausal symptoms will be excluded.
- Malignant condition of uterus, HIV, HBsAg, VDRL positive Infections (chlamydial infection, tubercular cervicitis etc) cervical endometriosis, decubitus ulcer, urethral caruncle, anovular bleeding.
- Patients having any major medical disorders (Thyroid disfunction, Hypertension, Haemophelia, Cystic glandular hyperplasia)
- Patient taking other treatment for Raktpradara**.**

D) Place of work: - This study was carried out in our Hospital's OPD of Stree Roga Prasuti Tantra.

E) Informed Consent: - The subject undergoing this study was informed about the nature & purpose of study and written consent for each patient in both groups was taken.

F) Material: [Drugs]

Jambu beej churna –Trial Drug.

Nagkeshar churna –Control Drug

G) Methods [Treatment Schedule]: – The selected patient will be treated under following groups

Group A (Trial Drug): - 30 patients will be given "Jambu beej churna"

- Dose: –each 5 gm bd
- Swaroop: -Churna
- Prayog: - Abhyantar.
- Sevan Kala: - Twice at Pragbhakta Kala.i.e.Before Meal.
- Anupana: -Mishreya

Group B (Control group): - 30 patient will given"Nagkeshar Churna".

- Dose: –5 gm B.D.
- Swaroop: -churna
- Prayog: - Abhyantar.
- Sevan Kala: - Twice at Pragbhakta Kala.i.e.Before Meal.
- Anupana: -Mishreya

H) DURATION OF TREATMENT: -

Total duration of the Treatment is for 03 successive menstrual cycles. Thus, Observations and Investigations necessary would be carried on the **1st, 3rd, 7th, 10th,** 15th **day of** first menstrual cycle and then on 5th day of next 2 menstrual. Thus, Conclusion will be made as per the Observations found.

ASSESSMENT CRITERIA: -

The effect of treatment assessed on the basis of relief of signs and symptoms of the diseases. Scoring pattern has been adopted to determine the relief in cardinal symptoms, which is given as below.

1)Duration of PV bleeding (Rajhapravrutikaal)

4 – 5 days	Grade 0
6 – 7 days	Grade 1
8 – 9 days	Grade 2
More than 10 days	Grade 3

2)Total blood loss according to avg. wt. of soaked pad during menstrual cycle

25-50 mg	Grade 0
50-75 mg	Grade 1
75-100 gm	Grade 2
More than 100 gms	Grade 3

3)Abdominal pain (Adhodar shool)

No pain	Grade 0
Mild (having pain can do routine work)	Grade 1
Moderate (can do work in two intermittent pain)	Grade 2
Severe (can't work bed ridden)	Grade 3

4) HB %

>10 gm%	Grade 0
10-8.5 gm%	Grade 1
8.5-7.5 gm%	Grade 2
7.5-7 gm%	Grade 3

5) Katishool

No pain	Grade 0
Pain increases due to heavy movement	Grade 1
Continuous pain during movement	Grade 2
Unabel to do any movement due to pain	Grade 3

6)Heart rate (Apex beat/min)

71-75	Grade 0
76-80	Grade 1
81-85	Grade 2
More than 85	Grade 3

7)Agnimandya (Sense of appetite in hrs)

6 -8 hrs	Grade 0
8 -10 hrs	Grade 1
10- 12 hrs	Grade 2
More than 12	Grade 3

OBSERVATIONS & RESULT

Duration of PV Bleeding: -

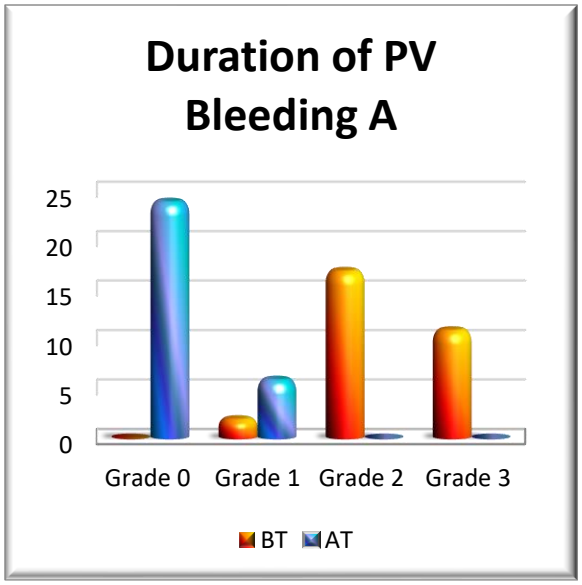
Table no: -1

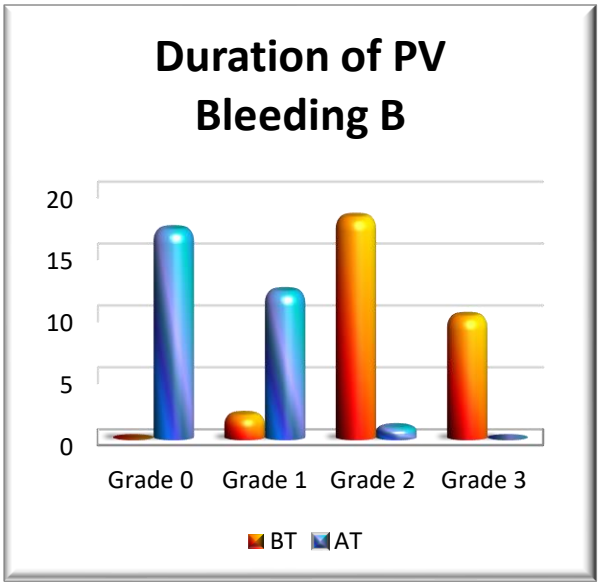
Duration of PV Bleeding	Group A		Group B	
	BT	AT	BT	AT
Grade 0	0	24	0	17
Grade 1	2	6	2	12
Grade 2	17	0	18	1
Grade 3	11	0	10	0
Total	30	30	30	30

Duration of PV Bleeding %	Group A		Group B	
	BT	AT	BT	AT
Grade 0	0%	80%	o%	56.66%
Grade 1	6.66%	20%	6.66%	40%
Grade 2	56.66%	0%	60%	3.33%
Grade 3	36.66%	0%	33.33%	0%
Total	100%	100%	100%	100%

Duration of PV Bleeding: -

GRAPH NO. 1.





Total Blood loss according to avg. wt. of soaked pad during: -
Table no .2

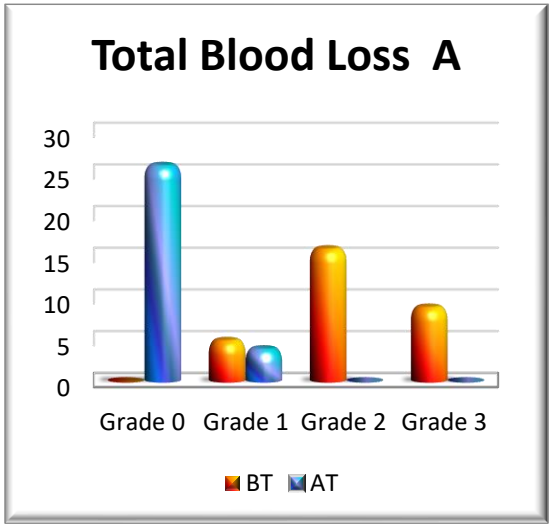
Total Blood Loss	Group A		Group B	
	BT	AT	BT	AT
Grade 0	0	26	0	15
Grade 1	5	4	6	14
Grade 2	16	0	21	1
Grade 3	9	0	3	0

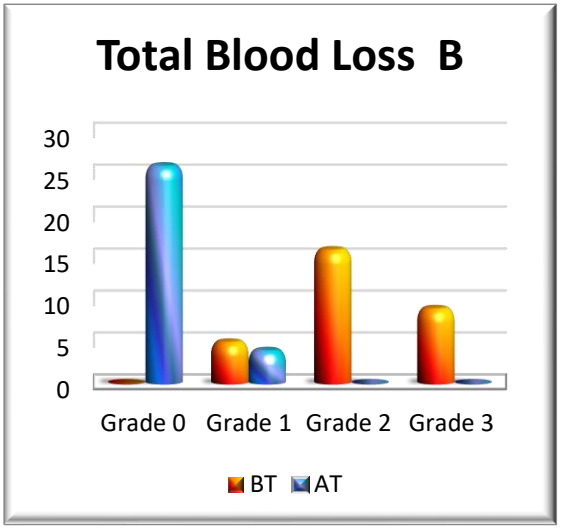
Total	30	30	30	30

Table no: -3

Total Blood Loss %	Group A		Group B	
	BT	AT	BT	AT
Grade 0	0%	86.66%	0%	50%
Grade 1	16.66%	13.33%	20%	46.66%
Grade 2	53.33%	0%	70%	3.33%
Grade 3	30%	0%	0%	0%
Total	100%	100%	100%	100%

Total Blood loss according to avg. wt. of soaked pad during: -
GRAPH NO.2&3





Abdominal Pain: -
Table no: -4

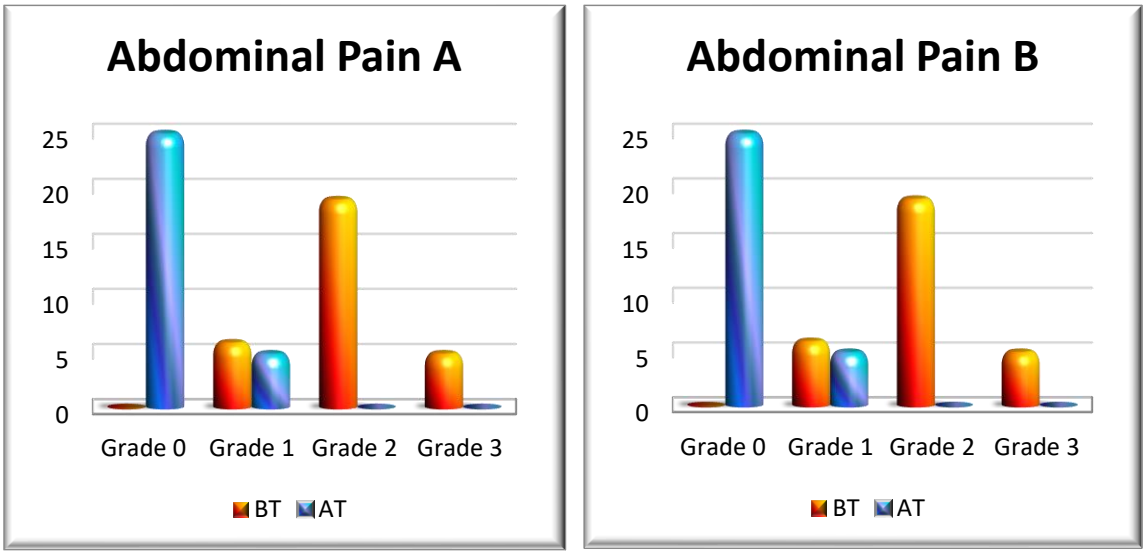
Abdominal Pain	Group A		Group B	
	BT	AT	BT	AT
Grade 0	0	25	0	18
Grade 1	6	5	8	10
Grade 2	19	0	15	2
Grade 3	5	0	7	0
Total	30	30	30	30

Abdominal Pain %	Group A		Group B	
	BT	AT	BT	AT
Grade 0	0%	83.33%	0%	60%
Grade 1	20%	16.66%	26.66%	33.33%
Grade 2	63.33%	0%	50%	6.66%
Grade 3	16.66%	0%	23.33%	0%

Total	30	30	30	30

Abdominal Pain: -

GRAPH NO.4



EFFECT OF THERAPHY AND COMPARATIVE ANALYSIS:

STATISTICAL ANALYSIS

TRIAL **GROUP A: - Table No 5**

SR NO	Symptoms/sign	GROUP	N	MEAN	VARIANCE	-+ SD	"t"	"P"value
1	Duration of PV bleeding	B. T	30	2.3	0.3552	0.596	15.9413	<0.05
		A.T.	30	0.2	0.1655	0.4068	15.9413	<0.05
2	Total Blood loss according to avg. wt. of soaked pad during	B. T	30	2.1333	0.4644	0.6815	14.3364	<0.05
		A.T.	30	0.1333	0.1195	0.3457	14.3364	<0.05
3	Abdomen pain (Adhodarshool)	B.T	30	1.9667	0.3782	0.615	13.6479	<0.05
		A.T.	30	0.1667	0.1437	0.3791	13.6479	<0.05
4	Hb%	B.T	30	1.3667	0.2402	0.4901	9.0567	<0.05
		A.T.	30	0.2667	0.2023	0.4498	9.0567	<0.05
5	Katishool	B.T	30	1.9	0.4379	0.6617	13.5288	<0.05
		A.T.	30	0.1	0.0931	0.3051	13.5288	<0.05
6	Agnimandya (Sense of Appetite in hrs)	B.T	30	1.6667	0.2989	0.5467	12.9833	<0.05
		A.T.	30	0.1333	0.1195	0.3457	12.9833	<0.05

GROUP B:- Table No 6

SR NO	Symptoms/sign	GROUP	N	MEAN	VARIANCE	-+ SD	"t"	"P"value
1	Duration of PV bleeding	B.T	30	2.2667	0.3402	0.5833	12.6104	<0.05
		A.T.	30	0.4667	0.3264	0.5713	12.6104	<0.05
2		B.T	30	1.9	0.3	0.5477	9.4587	<0.05

	Total Blood loss according to avg. wt. of soaked pad during	A.T.	30	0.5333	0.3264	0.5713	9.4587	<0.05
3	Abdomen pain (Adhodarshool)	B.T	30	1.9667	0.5161	0.7184	8.6054	<0.05
		A.T.	30	0.4667	0.3954	0.6288	8.6054	<0.05
4	Hb%	B.T	30	1.3333	0.2299	0.4795	5.5112	<0.05
		A.T.	30	0.5667	0.392	0.6261	5.5112	<0.05
5	Katishool	B.T	30	1.7667	0.392	0.6261	9.6446	<0.05
		A.T.	30	0.3667	0.2402	0.4901	9.6446	<0.05
6	Agnimandya (Sense of Appetite in hrs)	B.T	30	1.8	0.3034	0.5508	9.2017	<0.05
		A.T.	30	0.4667	0.3264	0.5713	9.2017	<0.05

GROUP COMPARE:-Table No.7

SR NO	Symptoms/sign	GROUP	N	MEAN	VARIANCE	$_{-}^{+}$ SD	"t"	"P"value
1	Duration of PV bleeding	GROUP A	30	0.2	0.1655	0.4068	-2.0827	<0.05
		GROUP B	30	0.4667	0.3264	0.5713		
2	Total Blood loss according to avg. wt. of soaked pad during	GROUP A	30	0.1333	0.1195	0.3457	-3.2808	<0.05
		GROUP B	30	0.5333				
3	Abdomen pain (Adhodarshool)	GROUP A	30	0.1667	0.1437	0.3791	-2.2379	<0.05
		GROUP B	30	0.4667	0.3954	0.6288		
4	Hb%	GROUP A	30	0.2667	0.2023	0.4498	-2.1315	<0.05
		GROUP B	30	0.5667	0.392	0.6261		
5	Katishool	GROUP A	30	0.1	0.0931	0.3051	-2.5301	<0.05
		GROUP B	30	0.3667	0.2402	0.4901		
6	Agnimandya (Sense of Appetite in hrs)	GROUP A	30	0.1333	0.1195	0.3457	-2.734	<0.05
		GROUP B	30	0.4667	0.3264	0.5713		

EFFECT OF THERAPIES: s
COMPARATIVE ANALYSIS:

STATISTICAL ANALYSIS: -

The information collected on the basis of observation, were subjected to statistical analysis in terms of percentage of relief, Mean, Standard Deviation (SD) and variance and by the use of unpaired t test, evaluate the significances at different levels i.e., at 0.05, 0.01 and 0.001 levels. The obtained results were interpreted as-

- Insignificant result - P > 0.05
- Significant result - P < 0.05
- Significant result - P < 0.01
- Highly significant result - P < 0.001

Data: - The data of patients is collected before treatment that is day 1st and the data collected after giving Jambu Beej Churna for 3 cycles of each patient.

Test: - For this study unpaired t test was applied.

Null Hypothesis: - There is no change in the data or symptoms score obtained before and after the treatment. So, Jambu Beej Churna is not effective in the Raktapradara.

Alternative Hypothesis: - The score of the symptoms is reduced after giving Jambu Beej Churna. So, Jambu Beej Churna is effective in the Raktapradara.

In the observation of Duration of PV bleeding, in Group A- Mean is 0.2, SD is 0.4068 & variance is 0.1655 and in group B-Mean is 0.4667, SD is 0.5713, variance is 0.3264, by unpaired t-test,P is less than 0.05, it means significant difference observed in Group A than Group B.

In the observation of Total Blood loss according to avg. wt. of soaked pad during, in Group A- Mean is 0.1333, SD is 0.3457 & variance is 0.1195 and in group B-Mean is 0.5333, SD is 0.5713 & variance is 0.3264, by unpaired t-test, P is less than 0.05, it means significant difference observed in Group A than Group B.

In observation of Abdomen pain,in Group A-Mean is 0.1667,SD is 0.3791 & variance is 0.1437 and in Group B-Mean is 0.4667, SD is 0.6288 & variance is 0.3954 , by unpaired t-test, P is less than 0.05, it means significant difference observed in Group A than Group B.

In the observation of HB%, in Group A-Mean is 0.2667, SD is 0.4498 & Variance is 0.2023 and in Group B-Mean is 0.5667, SD is 0.6261 & variance is 0.392, by unpaired t-test, P is less than 0.05, it means significant difference observed in Group A than Group B.

In the observation of Katishool, in Group A-Mean is 0.1, SD is 0.3051 & variance is 0.0,0931 and in Group B-Mean is 0.3667, SD is 0.4901 & variance is 0.2402, by unpaired t-test, P is less than 0.05, it means significant difference observed in Group A than Group B.

In the observation of Agnimandya, in Group A-Mean is 0.1333, SD is 0.3457 & variance is 0.1195 and in Group B-Mean is 0.4667, SD is 0.5713 & variance is 0.3264, by unpaired t-test, P is less than 0.05, it means significant difference observed in Group A than Group B.

RESULTS: -

From the above data analysis, it found that there is change in the score of symptoms before treatment and after treatment, that is the score is decreased and patients getting relief so the null hypothesis is rejected and alternative hypothesis is accepted that is Jambu Beej Churna shows highly significant results on Raktapradar.

OVERALL EFFECT OF THERAPY on 60 patients of Raktapradara
Tapble No.8.

Result	Group A		Group B	
	Number of patients	%	Number of patients	%
Complete remission (above75% to100%)	25	83.33	17	56.67
Marked improvement (above50%–upto75%)	5	16.66	12	40
Moderate improvement (above25%–upto50%)	0	0	1	3.33
Mild improvement **(up to 25 %)**	0	0	0	0

The table shows overall effect of therapy in both groups. 25 (83.33%) patients cured in group 'A'; 5 (16.33%) patients were marked improved by the treatment of Jambu beej churna.

Whereas 17 (56.67%) patients cured, 12 (40 %) patients were improved and 1 (3.33%) patient were not improved from the treatment of Nagkeshar churna in Group 'B'.

DISCUSSION:

Raja is an important factor for women. Shuddha raja or Artava is one of the most essential factors for healthy progeny, it gives the starting of reproductive period.

AGE: -Maximum patients were (43.33%) from 26-30yrs age group, followed by (31.66%) from 19-25yrs age group, (15%) from 31-35yrs age group, (6.66%) from 36-40yrsage group.s

PRAKRUTI: - Majority of patients belongs to Pitta-pradhanprakrutii.e (46.67%), (30%) patients belongs to kapha-pradhanprakruti and (23.33%) belongs to Vata-pradhanprakruti.

PARITY: - Majority of patients belongs to Multipara (33.33%), (30%) belongs to second para, (8.33%) belongs to student group. (28.33%) belongs to primigravida group, (8.33%) belongs to Nulpararus group.

DURATION OF PV BLEEDING: - In Group-A of Jambu beej Churna, duration of PV bleeding shows relief 80% which is statistically highly significant. While in Group-B of NagkesharChurnashows relief 56.66% which is statistically significant. Hence by using statistical test difference between the mean of two groups when compared with each other shows that Group-A is more effective on duration of PV bleeding than Group-B.

TOTAL BLOOD LOSS ACCORDING TO AVERAGE WEIGHT OF SOAKED PAD DURING MENSTRIAL CYCLE: - In

Group-A of Jambu beej churna, Quantity of PV bleeding shows relief 86.66 % which is statistically highly significant. While in Group-B of NagkesharChurnashows relief 50 % which is statistically significant.

ABDOMINAL PAIN: - In Group-A of Jambu Beej Churna, Abdominal Pain shows relief 83.33 % which is statistically highly significant. While in Control Group-B of NagkesharChurna shows relief 60 % which is statistically significant. Hence by using statistical test difference between the mean of two groups when compared with each other shows that Group-A is more effective on Abdominal pain than Group-B.

Hemoglobin %- In Group-A of Jambu Beej Churna, Heamoglobin shows relief 73.33% which is statistically highly significant. While in Control Group-B of Nagkeshar Churna shows relief 50% which is statistically significant.

Katishool: - In Group-A of Jambu Beej Churna, Katishool shows relief 90% which is statistically highly significant. While in Control Group-B of Nagkeshar Churna shows relief 63.33% which is statistically significant. Hence by using statistical test difference between the mean of two groups when compared with each other shows that Group-A is more effective on katishol than Group-B.

Agnimandya: - In Group-A of Jambu Beej Churna, Katishool shows relief 86.66% which is statistically highly significant. While in Control Group-B of NagkesharChurna shows relief 56.66% which is statistically significant. Hence by using statistical test difference between the mean of two groups when compared with each other shows that Group-A is more effective on Agnimandya than Group-B.

CONCLUSION:

In this present study total 60 patients were registered & distributed into two groups

Group-A- Trial Drug (Jambu beej Churna)

Group-B- Control Drug (Nagkeshar Churna)

It can be concluded that Jambu beej Churna (Trial drug) is quite effective on Raktapradar. Signs & Symptoms improves with a dose and duration mentioned in the Study. But Nagkeshar churna (Control drug) is found efficacious in comparison with Jambu beej Churna in Raktapradar disease. Nagkeshar Churna shows better Statistical results than the Trial drug.

trial drug may be used in -

The trial drug can be used in Vyadhi with Alpa Bala,Sukumara Rugna.

It can be used at earlier stages of the diseases.

Guna: Laghu Ruksha

Ras: - Kashay Mishreyar Amla

Virya: Sheeta

Vipaka: Katu

Doshagnata: – It increases Vata but balances Kapha and Pitta

Majority of drug in JAMBU BEEJ churna Katu Vipaki & hence they can produce Upadravatmak lakshana in Pitta or Vata prakruti patients Due to kashay ras and sheet virya jambu beej churna is raktasthambak so it is beneficial in rakta pradar. The control drug contain large no.of drugs which shows katu vipak and hencethe control drug is prone to producePitta and Vata. Thus, we can safely use the trial drug in Sukumara, Alpa Bala Rugna and Pitta Prakruti Rugna. Thus, more research in this work is necessary, to boost up the results which can serve the mankind.

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