



Research Article

**A CLINICAL STUDY TO EVALUATE EFFICACY OF KVGAP'S FEMICARE SYRUP ON RAKTAPRADARA W.S.R TO DYSFUNCTIONAL UTERINE BLEEDING**

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**ABSTRACT**

Dysfunctional uterine bleeding (*Raktapradara*) is the commonest gynecological disorder affecting the quality women's life of reproductive age group. A clinical study was conducted with KVGAP'S Femicare Syrup on 28 patients of DUB. KVGAP'S Femicare syrup is a polyherbal Ayurvedic formulation prepared from ingredients like *Ashoka*, *Ashwagandha*, *Gokshura*, *Guduchi*, *Shatavari*, *Manjistha*, *Usheera*, *Kumari*, *Sariva*, *Pippali*, and *Shilajathu*. The parameters assessed were number of bleeding episodes, excessive bleeding, investigators global assessment scale, VAS for pain, participants overall assessment scale, clot and interval (number of days of the cycle). Patients were assessed at the beginning of the trail, after 1 month and after 2 months. 56.52%, 73.08%, 77.6%, 85%, 81.93%, 100% improvement were observed in the clinical parameters assessed (number of bleeding episodes, excessive bleeding, investigators global assessment scale, VAS for pain, participants overall assessment scale, clot) respectively. Results were statistically significant. Interval didn't show any changes. Out of 28 patients in this study, 1 patient shown mild improvement, 11 patients (39%) were shown moderate improvement and 16 patients (57%) had marked improvement. Overall effect of the treatment was 77.31%. This study showed that KVGAP'S Femicare syrup showed promising results in treating DUB. Hence it can be concluded that KVGAP'S Femicare Syrup is effective and safe in the management of dysfunctional uterine bleeding.

**INTRODUCTION**

Menstruation denotes healthy state of female reproductive system, but if the cycle turns to be abnormal with excessive, prolonged bleeding, associated with pain during the intermenstrual period suggestive of underlying pathology. The natural phenomenon of regular cyclic menstruation reflects the relationship between the endometrium and its regulatory factors. DUB (Dysfunctional Uterine Bleeding) is one of the commonest gynecological problems encountered in day today practice. DUB can be defined as "abnormal uterine bleeding without any clinically detectable organic pelvic pathology- tumor, inflammation or pregnancy."<sup>[1]</sup>

Bleeding may be abnormal in frequency, amount or duration or combination of any three<sup>[2]</sup>. Ninety percent of DUB is anovulatory. The prevalence varies widely but an incidence of 10 percent amongst new patients attending the outpatients seems logical.<sup>[3]</sup> *Raktapradara* described in Ayurveda can be best correlated with DUB. Ayurveda has effective combination of drugs by which management of *Raktapradara* can be effectively done. In the light of above, it may be worthwhile to explore the potential of KVGAP'S Femicare Syrup in *Rakta Pradara*.

**OBJECTIVE**

To evaluate the efficacy of KVGAP'S Femicare Syrup in *Rakta Pradara*.

**METHODOLOGY**

An open non-randomized clinical trial has been conducted in 30 patients selected from and Outpatient Department of KVG Ayurveda Medical College and Hospital, Ambateadka, Sullia, with the help of various Ayurveda physicians. 2 patients dropped out during the trail.

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**Inclusion Criteria**

- Women: 18 years or older
- With diagnosis of dysfunctional uterine bleeding without organic pathology
- With at least one of the following symptoms: painful, prolonged, frequent or excessive bleeding.

**Exclusion Criteria**

- The use of estradiol valerate, steroidal oral contraceptives, or any drug that could alter oral contraception metabolism will be prohibited during the study.

- Women having history of endometrial ablation or dilatation or curettage within 2 months prior to study start.

**Trial Drug**➤ **KVGAP'S Femicare Syrup****Preparation of the Trial Drug**

KVGAP'S Femicare Syrup was manufactured in KVG Ayurveda Pharma and Research centre, Sullia, adhering to strict GMP guidelines.

The composition of KVGAP'S Femicare Syrup is as per the table.

**Composition:** Each 5ml contains

**Table 1: Showing composition of KVGAP'S Femicare Syrup**

S.No	Botanical Name- Sanskrit Name	Part Used	Forms of Ingredient	Qty	UoM	Reference	Page No
1	<i>Saraca ashoka - Ashoka</i>	Bark	Aqueous Extract	813.0000	mg	API	14
2	<i>Withania Somnifera - Ashwagandha</i>	Root	Aqueous Extract	407.0000	mg	API	15
3	<i>Tribulus terrestris - Gokshura</i>	Fruit	Aqueous Extract	407.0000	mg	API	40
4	<i>Tinospora Cordifolia - Guduchi</i>	Stem	Aqueous Extract	407.0000	mg	API	41
5	<i>Asparagus racemosus - Shatavari</i>	Root	Aqueous Extract	407.0000	mg	API	122
6	<i>Rubia cordifolia - Manjistha</i>	Stem	Aqueous Extract	407.0000	mg	API	169
7	<i>Vetivera Zizanoides - Usheera</i>	Root	Aqueous Extract	407.0000	mg	API	219
8	<i>Aloe vera - Kumari</i>	Leaf	Aqueous Extract	407.0000	mg	API	62
9	<i>Hemidesmus indicus - Sariva</i>	Root	Aqueous Extract	1220.0000	mg	API	107
10	<i>Piper longum - Pippali</i>	Fruit	Aqueous Extract	8.1300	mg	API	91
11	Asphaltum - Shilajatu - Shodita	--	Powder	4.0400	mg	CR	50
12	Sugar - Sharkara	--	Powder	3250.0000	mg		0

**Preservatives and Excipients**

S. No	Excipient Name	Quantity	UoM	Used As
1	Sodium benzoate	0.0200	gm	Preservative
2	Methyl paraben	0.0060	gm	Preservative
3	Propyl paraben	0.0006	gm	Preservative

**Method of Preparation:** Coarse powders of all the ingredients were prepared and sufficient quantity of RO/UV treated potable water was added to it and reduced to 1/4<sup>th</sup>, filtered and sugar candy was added, stirred well till it attains syrup consistency. Sufficient quantity of permitted preservatives: (Sodium Benzoate- 0.53%, Methyl paraben- 0.13%, Propyl paraben- 0.013%) were added and after cooling packed in air tight containers.

**Treatment Schedule**

KVGAP'S Femi care syrup was administered at the dose of 10ml twice daily orally for 2 months. Patients were advised to restrict themselves to the KVGAP'S Femicare Syrup as the only treatment for their complaints and resort to no other active treatment intervention during the study period was allowed.

**Assessment Criteria**

The cases were assessed by subjective and objective parameters, before and after 1 month and 2 months of treatment. The parameters assessed were number of bleeding episodes, excessive bleeding, investigators global assessment scale, VAS for pain, participants overall assessment scale.

**Assessment Scale**

To estimate the severity of the disease and to record the clinical outcome, the following pattern of scale was prepared and used.

**No. of Bleeding Episodes**

G<sub>0</sub> – No Bleeding episode

G<sub>1</sub> – Bleeding episode < 4 days.

G<sub>2</sub> – Bleeding episode 4-7 days

G<sub>3</sub> – Bleeding episode > 7 days

**Excessive bleeding:** Number of pads used per day

**VAS for pain:** 10cm scale was adopted

**Investigators Global Assessment scale:** 5 point measurement scale was adopted.

**Participants Overall Assessment Scale:** 5 point scale was adopted.

**Clot**

G<sub>0</sub> – Absent

G<sub>1</sub> – Present

**Interval:** Number of days of cycle.

**RESULTS**

In the present study, 28 patients suffering from DUB fulfilling the inclusion criteria were studied and were randomly selected. Observation of each patient was done thoroughly. Necessary charts and graphs were made accordingly.

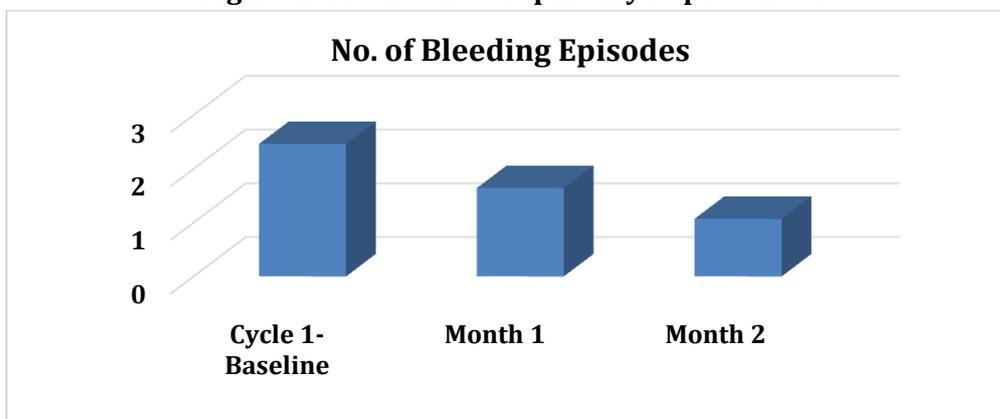
**Table 2: Showing Effect of KVGAP'S Femicare Syrup on Number of bleeding episodes in DUB**

Symptom	Measures				%	SD (+/-)	SE (+/-)	t value	p value
	Cycle 1- Baseline								
No. of Bleeding episodes	2.46	Month 1	1.64	0.82	33.33	0.670	0.129	6.49	<0.05
		Month 2	1.07	1.39	56.52	0.875	0.168	8.42	<0.05

**Effect of KVGAP'S Femi care Syrup on Number of Bleeding Episodes**

This study consisting of 28 patients of DUB with no. of bleeding episodes revealed the result of it as shown in the table No 02. Statistical analysis showed that the mean score which was 2.46 before treatment, was reduced to 1.64 after 1 month of treatment and reduced to 1.07 after 2 months with 56.52% improvement, and there is a statistically significant change. (P<0.05)

**Figure 1: Results are Graphically Represented**



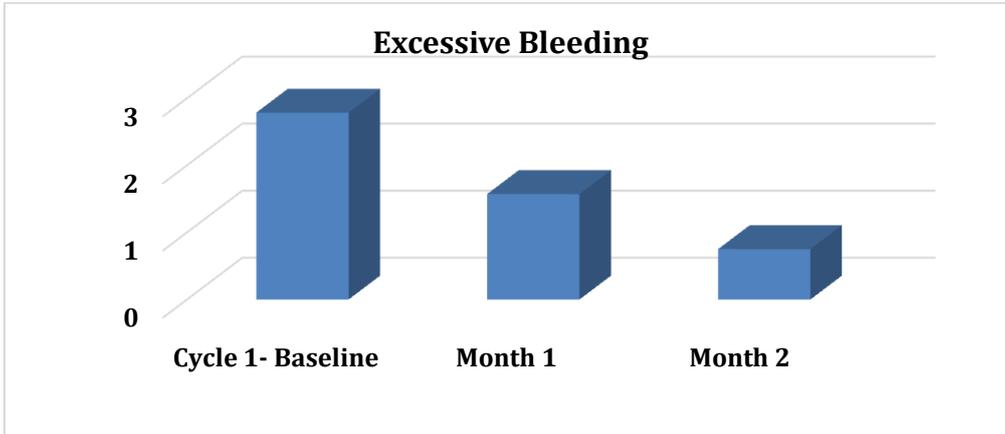
**Table 3: Showing Effect of KVGAP'S Femicare Syrup on Excessive Bleeding in DUB**

Symptom	Measures				%	SD (+/-)	SE (+/-)	t value	p value
	Cycle 1-Baseline								
Excessive Bleeding	2.78	Month 1	1.57	1.21	43.59	0.568	0.109	11.31	<0.05
		Month 2	0.75	2.04	73.08	0.793	0.153	13.59	<0.05

**Effect on Excessive Bleeding**

This study consisting of 28 patients of DUB with excessive bleeding revealed the result of it as shown in the table No 03. Statistical analysis showed that the mean score which was 2.78 before treatment, was reduced to 1.57 after 1 month of treatment and reduced to 0.75 after 2 months of treatment with 73.08% improvement, and there is a statistically significant change. (P<0.05)

**Figure 2: Results are Graphically Represented**



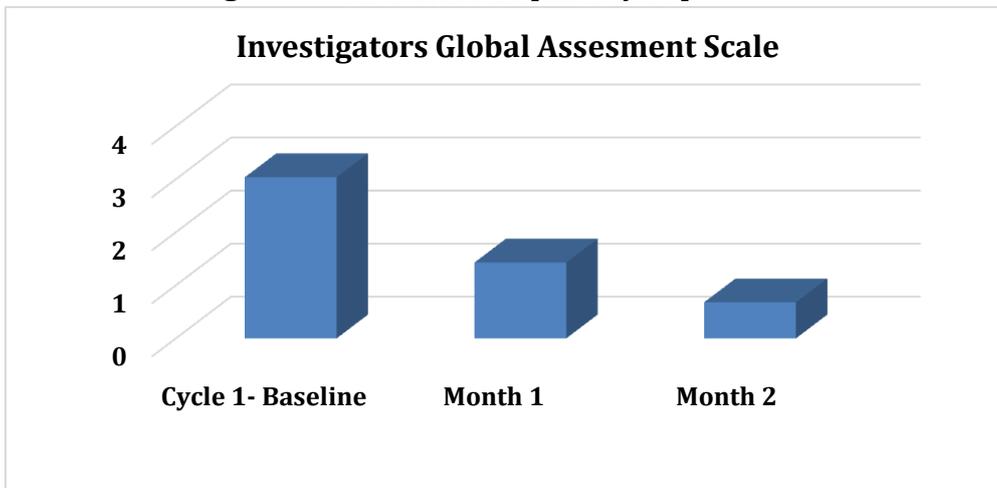
**Table 4: Effect of KVGAP'S Femicare Syrup on Investigators Global Assessment Scale in DUB**

Symptom	Measures				%	SD (+/-)	SE (+/-)	t value	p value
	Cycle 1-Baseline								
Investigators Global Assessment Scale	3.04	Month 1	1.43	1.61	52.94	0.567	0.109	15.00	<0.05
		Month 2	0.68	2.36	77.65	0.621	0.120	20.07	<0.05

**Effect on Investigators Global Assessment Scale**

This study consisting of 28 patients of DUB with Investigators Global Assessment Scale revealed the result of it as shown in the table No 04. Statistical analysis showed that the mean score which was 3.04 before treatment, was reduced to 1.43 after 1 month of treatment and reduced to 0.68 after 2 months of treatment with 77.65% improvement, and there is a statistically significant change. (P<0.05)

**Figure 3: Results are Graphically Represented**



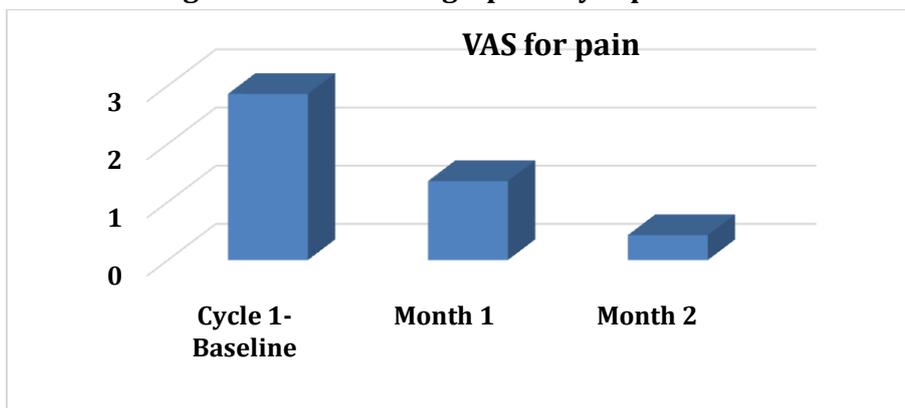
**Table 5: Effect of KVGAP'S Femicare Syrup on VAS for Pain in DUB**

Symptom	Measures				%	SD (+/-)	SE (+/-)	t value	p value
	Cycle 1-Baseline								
VAS for Pain	2.86	Month 1	1.36	1.50	52.50	0.694	0.134	11.44	<0.05
		Month 2	0.43	2.43	85.00	1.034	0.199	12.43	<0.05

**Effect of KVGAP'S Femicare Syrup on VAS for Pain**

This study consisting of 28 patients of DUB with VAS for pain revealed the result of it as shown in the table No 05. Statistical analysis showed that the mean score which was 2.86 before treatment, was reduced to 1.36 after 1 month of treatment and reduced to 0.43 after 2 months of treatment with 85% improvement, and there is a statistically significant change. (P<0.05)

**Figure 4: Results are graphically represented**



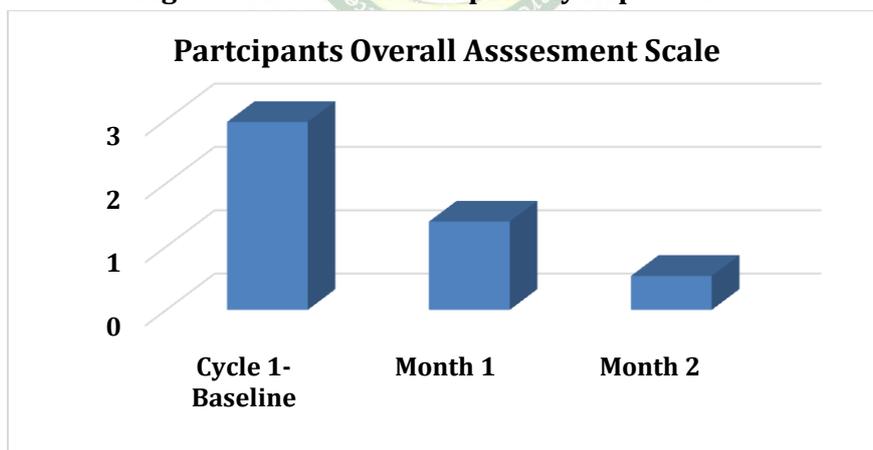
**Table 6: Effect of KVGAP'S Femicare Syrup on Participants Overall Assessment Scale in DUB**

Symptom	Measures				%	SD (+/-)	SE (+/-)	t value	p value
	Cycle 1-Baseline								
Participants Overall Assessment Scale	2.96	Month 1	1.39	1.57	53.01	0.634	0.122	13.11	<0.05
		Month 2	0.54	2.43	81.93	0.836	0.161	15.38	<0.05

**Effect on Participants Overall Assessment Scale**

This study consisting of 28 patients of DUB with Participants Overall Assessment Scale: Revealed the result of it as shown in the table No 06. Statistical analysis showed that the mean score which was 2.96 before treatment was reduced to 1.39 after 1 month of treatment and reduced to 0.54 after 2 months of treatment with 81.93% improvement, and there is a statistically significant change. (P<0.05)

**Figure 5: Results are Graphically Represented**



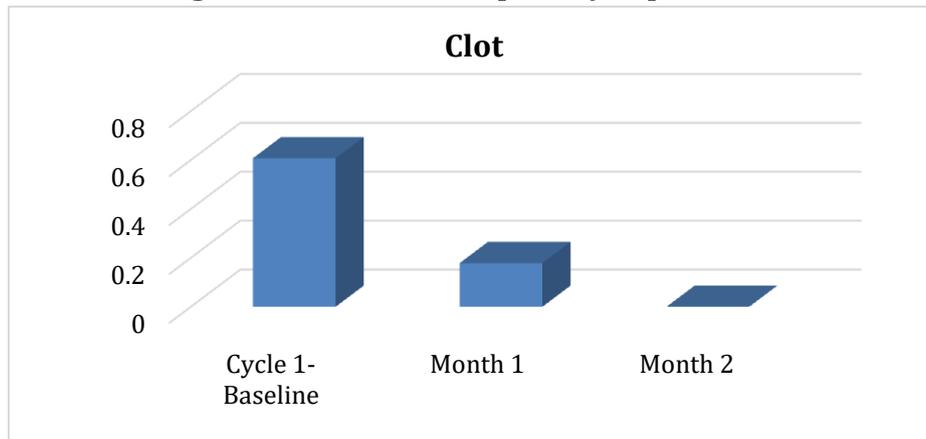
**Table 7: Effect of KVGAP'S Femi care Syrup Clot in DUB**

Symptom	Measures				%	SD (+/-)	SE (+/-)	t value	p value
	Cycle 1-Baseline								
Clot	0.61	Month 1	0.18	0.43	70.59	0.504	0.097	4.50	<0.05
		Month 2	0.00	0.61	100.00	0.497	0.096	6.46	<0.05

**Effect on Clot**

This study consisting of 28 patients of DUB with clot revealed the result of it as shown in the table No 07. Statistical analysis showed that the mean score which was 0.61 before treatment was reduced to 0.18 after 1 month of treatment and reduced to 0.00 after 2 months of treatment with 100% improvement, and there is a statistically significant change. (P<0.05)

**Figure 6: Results are Graphically Represented**



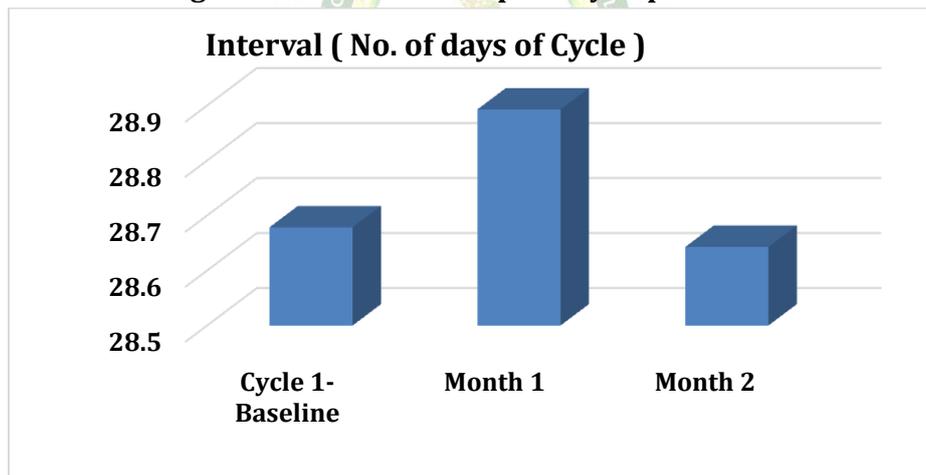
**Table 8: Effect of KVGAP'S Femi care Syrup on Interval (No of days of Cycle) in DUB**

Symptom	Measures			%	SD (+/-)	SE (+/-)	t value	p value	
	Cycle 1-Baseline	Month 1	Month 2						
Interval ( No of days of Cycle )	28.68	Month 1	28.89	-0.21	-0.75	3.745	0.721	-0.30	>0.05
		Month 2	28.64	0.04	0.12	5.066	0.975	0.04	>0.05

**Effect on Interval (No. of days of Cycle)**

This study consisting of 28 patients of (disease name) with interval (no of days of cycle) revealed the result of it as shown in the table No 08. Statistical analysis showed that the mean score which was 28.68 before treatment was increased to 28.89 after 1 month of treatment and reduced to 28.64 after 2 months of treatment with 0.12% improvement, and there is a statistically no significant change. (P>0.05)

**Figure 7: Results are Graphically Represented**



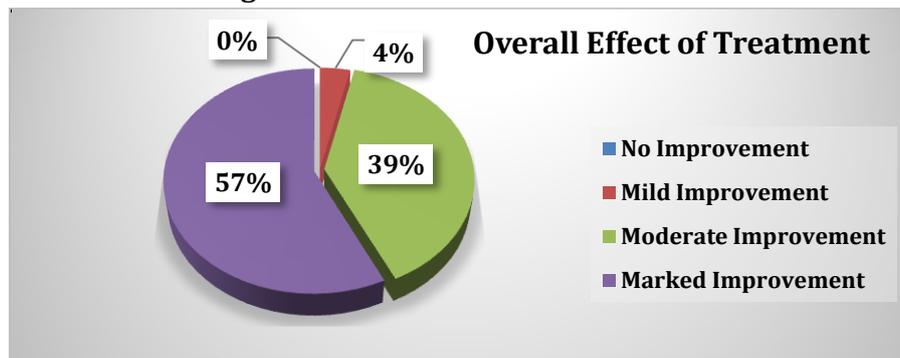
**Table 9: Overall Effect of Treatment**

Overall Effect of Treatment		
Grading	Relief in Percentage	Relief in Patients
No improvement	0 - 25%	0
Mild improvement	26 - 50 %	1
Moderate improvement	51 - 75 %	11
Marked improvement	76 - 100 %	16

In overall effect of treatment in DUB, out of 28 patients in this study, 11 patients (39%) were getting moderate improvement and 16 patients (57%) were getting marked improvement.

Overall effect of the treatment is 77.31%.

**Figure 8: Overall Effect of Treatment**

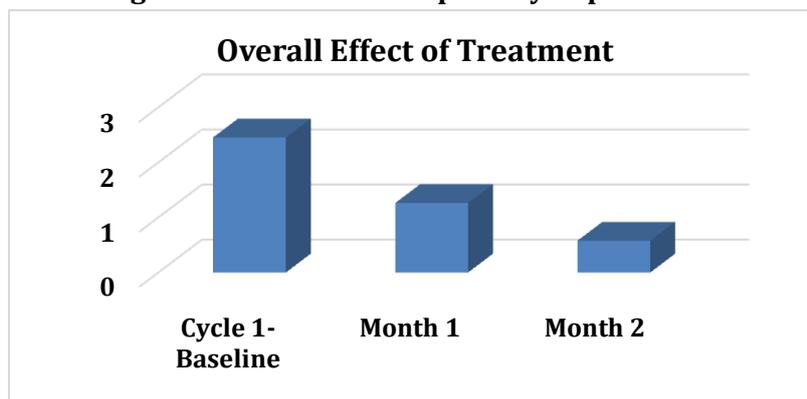


**Table 10: Effect of KVGAP'S Femi care Syrup on Overall Effect of Treatment**

BT	One Month	Two Months	SD	SE	t Value	P Value
2.45	1.26	0.58	0.381	0.073	19.12	<0.05

The overall effect of treatment, statistical analysis showed that the mean score which was 2.45 before treatment was reduced to 0.58 after follow up, and there is a statistically significant change. (P<0.05)

**Figure 9: Results are Graphically Represented**



**DISCUSSION**

Dysfunctional uterine bleeding is serious health concern in women affecting their quality of life, interfere their social, emotional and physical life. This study was done on 28 patients of DUB, with KVGAP'S Femicare Syrup observed a significant reduction in the mean scores of excessive bleeding condition and subjective evaluation revealed remarkable improvement. Observed good result of KVGAP'S Femicare Syrup, might be due to haemostatic, anti-spasmodic action of its ingredients, and *Sthambhaka* in quality. *Ashoka* has got anti hemorrhagic property.<sup>[4]</sup> *Ashwagandha* extract proved to improve luteinizing hormone and follicular stimulating hormone balance<sup>[5]</sup>. *Gokshura* is reported to have analgesic effect. Study revealed that Analgesic effect of extract of *Tribulus terrestris* is lower than morphine and higher than acetylsalicylic acid (aspirin) in both tests.<sup>[6]</sup> *Tinospora cordifolia* is effective immunomodulator.<sup>[7]</sup> *A. racemosus* contain saponins which hinder the oxytocic activity on uterine musculature, thereby maintaining the spontaneous uterine motility, confirming its utility in dysmenorrhea which comprises of painful menstruation without significant pelvic pathology<sup>[8]</sup>. Clinical study done on *Manjistha* showed statistically significant results in dysmenorrheal.<sup>[9]</sup> Anxiolytic

property of *Usheera*<sup>[10]</sup> helps to relieve the stress associated with DUB. *Aloe vera* inhibits the cyclooxygenase pathway and reduces prostaglandin E2 production from arachidonic acid, thus exhibiting anti inflammatory activity.<sup>[11]</sup> *Sariva* is reported of having analgesic<sup>[12]</sup> and anti-inflammatory analgesic activity<sup>[13]</sup>. *Pippali* acts as bioavailability enhancer.<sup>[14]</sup> *Shilajith* has got ovulation inducing activity.<sup>[15]</sup> Overall effects of these drugs, helps in relieving clinical features of the DUB. The aetiopathology of *Raktapradara*, involves *Pitta* and *Vata* as main *Doshas* and *Rakta* as *Dhooshya*. Dominant drugs have got *Sheeta veerya*, *Kashaya Tikta madhura rasa* which might have acted as *Pitta shamana*, *Raktaprasadana* thereby removing *Pittavarana* achieving *Samprapthi Vighatana*. The aggravated *Vata* might have been alleviated by the *Madhura*, *Snigdha* properties of *Gokshura* and *Shatavari*. Majority of ingredients are having *Sthambhaka* property. Thus drug action can be explained on the basis of Ayurvedic parlance. There were no clinically significant adverse reactions either reported or observed during the entire study period and overall compliance to the treatment was excellent.

## CONCLUSION

KVGAP'S Femi care Syrup was found to be effective in dysfunctional uterine bleeding. Out of 28 patients in this study, 1 (4%) patient showed mild improvement, 11 patients (39%) had moderate improvement and 16 patients (57%) had marked improvement. Overall effect of the treatment was 77.31%. This study showed promising results in treating DUB. Hence it could be concluded that KVGAP'S Femicare Syrup is effective and safe in the management of dysfunctional uterine bleeding.

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