

AN OPEN RANDOMIZED COMPARATIVE CLINICAL STUDY OF TRIPHALADI KWATHA AND VIDANGARAJANYADI KWATHA IN PRAMEHA W.S.R. TO TYPE II DIABETES MELLITUS

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ABSTRACT

Objectives: To evaluate the therapeutic effect of *Triphaladi Kwatha* in *Prameha* / Diabetes Mellitus. To evaluate the therapeutic effect of *Vidangarajanyadi Kwatha* in *Prameha* / Diabetes Mellitus. To compare the therapeutic effect of *Triphaladi Kwatha* and *Vidangarajanyadi Kwatha* in patients suffering from *Prameha* / Diabetes Mellitus. **Methodology:** An open randomized comparative clinical study was planned to evaluate the effect of *Triphaladi Kwatha* and *Vidangarajanyadi Kwatha* in *Prameha* w.s.r. to type 2 Diabetes Mellitus. The study was conducted on patients of S.D.M. of Ayurveda, Udupi with *Prameha*. Total 30 patients randomly grouped into two groups of 15 each by using a randomization method. In Group A (TP Group) patients were orally treated with *Triphaladi Kwatha* in a dose

of 50ml twice a day before food for 28 days and Group B (VR Group) patients were orally treated with *Vidangarajanyadi Kwatha* in a dose of 50ml twice a day before food for 28 days. Assessment was done on 0th 28th and 56th day. Subjective and objective parameters were assessed before and after treatment on 0th and 28th day. Later the results analyzed statistically. **Results:** Both groups had statistically significant results in most of the parameters. Comparing the effect of drugs showed no statistical significance in any parameters. This showed that effect by the two formulations is almost equal without any much difference

statistically. **Conclusion:** The *Triphaladi Kwatha* and *Vidangarajanyadi Kwatha* are ideal medicines for the patients suffering with *Prameha* in reducing the clinical symptoms of the diseases as well as in reduction of hyperglycemia.

KEYWORDS: Prameha, Diabetes Mellitus, *Triphaladi Kwatha*, *Vidangarajanyadi Kwatha*

INTRODUCTION

Prameha is a *Santharpanajanya Vikara* and also included under the *Ashtamahagada*.^[1] It involves all the three *dosha* (*Vata*, *Pitta*, *Kapha*) and ten *Dushya* (*Rasa*, *Rakta*, *Mamsa*, *Meda*, *Sukra*, *Ambu*, *Vasa*, *Lasika* and *Ojus*).^[2] Indulgence of the etiological factors related to *Prameha* results in *Aparipakva Vata*, *Pitta*, *Kapha* and *Meda* which further proceed through the *Mootravaha Srotas* to get localized in the *Bastimukha* and thus leading to disease *Prameha*.^[3] Based on the symptoms *Prameha* can be compared as Diabetes Mellitus.

Diabetes Mellitus refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. Depending on the etiology of the Diabetes Mellitus, factors contributing to hyperglycemia include reduced insulin secretion, decreased glucose utilization, and increased glucose production.^[4] It has many sub classifications, including type 1, type 2, maturity-onset diabetes of the young (MODY), gestational diabetes, neonatal diabetes, and steroid-induced diabetes. Type 1 and 2 Diabetes Mellitus are the main subtypes. The diagnosis of type 1 Diabetes Mellitus is usually through a *characteristic* history supported by elevated serum glucose levels (fasting glucose >126 mg/dL, random glucose over 200 mg/dL, or hemoglobin A1C (HbA1c exceeding 6.5%) with or without antibodies to glutamic acid decarboxylase (GAD) and insulin. Fasting glucose levels and HbA1c testing are useful for the early identification of type 2 diabetes mellitus. Pre diabetes, which often precedes T2DM, presents with a fasting blood glucose level of 100 to 125 mg/dL or a 2-hour post-oral glucose tolerance test (post-OGTT) glucose level of 140 to 200 mg/dL.^[5]

As of 2019, an estimated 463 million people had diabetes worldwide (8.8% of the adult population) with type 2 diabetes making up about 90% of the cases. Rates are similar in women and men. In 2019, diabetes resulted in approximately 4.2 million deaths. It is the 7th leading cause of death globally.^[6] Until recently; India had more diabetics than any other country in the world, according to the International Diabetes Foundation, although the country has now been surpassed in the top spot by China. Diabetes currently affects more than 62 million Indians, which is more than 7.2% of the adult population. Among young and

middle aged adults the prevalence of diabetes is 6.7% and pre-diabetes is 5.6% according to the National Family Health Survey-4. The average age on onset is 42.5 years.^[7]

The line of treatment of *Prameha* depends on its *Samprapti*, either *Avaranajanya* or *Dathukshayajanya*. *Shodhana* will be the line of treatment if *Apathyanimittaja Nidana* with *Avarana* causes *Sthoola Prameha*, where as in *Sahaja Nidana* causing *Dhatukshaya* leading to *Krsha Prameha Shamana* will be the treatment. Among the 20 types of *Prameha*, 10 *Kaphaja Prameha* are said to be *Sadhya* due to *Samakriyatvat*, 6 *Pittaja Prameha* are considered as *Yapya* because of *Vishamakriyatvat* and the 4 *Vataja Prameha* are *Asadhya* due to *Mahatyayatvat*.

Triphaladi Kwatha is mentioned in *Yogarathnakara* as an effective treatment in *Prameha* which contains *Triphala*, *Devadaru*, *Daruharidra* and *Mustha*.^[8] *Triphaladi Kwatha* acts as *Lekhaniya*, *Virechanopaga*, *Kaphahara* and *Medohara*. *Vidangarajanyadi Kwatha* is mentioned in *Yogarathnakara* in *Dusthara Prameha* which contains *Vidanga*, *Haridra*, *Yashtimadhu*, *Nagara*, and *Gokshura*.^[8] It has *Vata-Kaphahara*, *Medohara*, *Lekhaniya* and *Mutravirechaniya* effect.

There are many studies done to evaluate the efficacy of *Ayurvedic* formulations in *Prameha* / *Madhumeha* showing positive results. However, study of formulations with both herbal and mineral origin drugs can be done to get best outcome owing to their independent attributes as well as their combined action.

METHODOLOGY

Ethical committee clearance has been done.

Reference number:- SDMCAU/ACA-49/ECH 12/2020-21.

Objectives of the study

- To evaluate the therapeutic effect of *Triphaladi Kwatha* in *Prameha* / Diabetes Mellitus.
- To evaluate the therapeutic effect of *Vidangarajanyadi Kwatha* in *Prameha* / Diabetes Mellitus.
- To compare the therapeutic effect of *Triphaladi Kwatha* and *Vidangarajanyadi Kwatha* in patients suffering from *Prameha* / Diabetes Mellitus.

Source of data

Minimum 30 Patients diagnosed as *Prameha* fulfilling diagnostic, inclusion and exclusion criteria were taken for study from OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka. *Triphaladi Kwatha* and *Vidangarajanyadi Kwatha* were prepared in SDM Ayurveda Pharmacy, Udupi, Karnataka.

Method of collection of data

The patients were selected irrespective of gender, caste, race, based on the diagnostic, inclusion and exclusion criteria. The selected patients were invited to participate the study after signing the informed consent and then registered for clinical trial. A special proforma was prepared with detailed history taking, included signs and symptoms as mentioned in Ayurveda as well as other allied sciences.

Accordingly, selected patients were subjected to detailed clinical history and complete physical examination. As per the intervention protocol these subjects were given with *Triphaladi Kwatha* or *Vidangarajanyadi Kwatha* for respective groups for the stipulated period. The primary and secondary outcome measures are assessed before and after the intervention.

Design of the study:

Study type	: Interventional
Estimated enrollments	: 30 Patients
Allocation	: Randomized
Endpoint classification	: Comparative study
Intervention model	: Double group
Primary purpose	: Treatment
Masking	: Open label study

Intervention

30 patients were randomly grouped into two groups of 15 each by using a randomization method. Patients who are already on other antidiabetic drugs were advised to continue the same and trial drugs are given in addition to their respective groups.

Group A – *Triphaladi kwatha* group

Selected patients were orally treated with *Triphaladi Kwatha* in a dose of 50ml twice a day before food for 28 days.

Group B – *Vidangarajanyadi kwatha* group

Selected patients were orally treated with *Vidangarajanyadi Kwatha* in a dose of 50ml twice a day before food for 28 days.

Duration of clinical study:

Intervention : 28 days

Follow up : 28days

Total duration : 56 days

Diagnostic criteria:^[9]

Patients fulfilling the following criteria:

- 1) Signs and symptoms of *Prameha* that mentioned in *Ayurvedic* texts and allied medical science.
- 2) Fasting Blood Sugar Level ≥ 126 mg/dl (7.0mmol/l). Fasting is defined as no caloric intake for at least 8-10 Hours .
- 3) Two-hour plasma glucose ≥ 200 mg/dl.

Inclusion criteria:

- 1) Patients fulfilling the diagnostic criteria.
- 2) Patients between the age group of 30 to 70 years of either sex.
- 3) Fasting Blood Sugar Level 126 to 220 mg/dl.
- 4) Post Prandial Blood Sugar level ranging 140 to 280 mg/dl.

Exclusion criteria:

- 1) Type 1 DM.
- 2) Diabetic complications like Cardiomyopathy, Neuropathy, Nephropathy, Retinopathy, Diabetic ketoacidosis
- 3) Any systemic disorders
- 4) During any medical or surgical emergency conditions
- 5) Pregnant and Lactating women.
- 6) Had participated in any clinical trial within 3 months of screening.

Assessment criteria:

Assessment was done on the basis of subjective and objective criteria before, during and after the treatment i.e., on 0th day, 14th day, 28th day, 56th day. Statistical analysis was done using paired 't' test and Wilcoxon signed rank test on comparing 0 to 28th day within the group and in between the group it will be compared using unpaired 't' test and Mann Whitney test, using Sigma Plot software version 14.0.

1) Objective parameters:

It includes estimation of

- Fasting Blood Sugar Level
- Post Prandial Blood Sugar Level
- Fasting urine sugar level
- Post Prandial urine sugar level

2) Subjective parameters:

Grading will be given to all the parameters and statistical analysis will be done.

- *Prabhoota Mootrata*
- *Pipasa adhikya*
- *Kshuda adhikya*
- *Dourbalya*
- *Mukhatalushosha*
- *Kara Pada Daha*
- *Kara Pada Suptata*
- *Shareerabharahani*
- *Shithilangata*

Before and at the end of the therapy on 28th day.

Table 1: Grading of assessment parameters.

Sl. No.	Criteria	Details	Score
1	<i>Prabhoota Mootrata</i> (Polyuria)	3 to 5 times/day, rarely at night	0
		5 to 7 times/day, 1-2 times at night	1
		7 to 10 times/day, 3-4 times at night	2
		10 to 12 times/day, 3-4 times at night	3
2	<i>Pipasaadhikya</i> (Polydipsia)	Intake of water 5-7 times/24 hours with quantity 1.5-2.5 Litre/24 hours	0
		Intake of water 7-9 times/24 hours with	1

		quantity 2.5-3.0 Litre/24 hours	
		Intake of water 9-11 times/24 hours with quantity 3.0-3.5 Litre/24 hours	2
		Intake of water >11 times/24 hours with quantity >3.5 Litre/24 hours	3
3	<i>Kshudaadhikya</i> (Polyphagia)	Normal meals	0
		2 Main meals, Light breakfast 2-3/day	1
		2 Main meals, Light breakfast 3-5/day	2
		2 Main meals, Light breakfast >5/day	3
4	<i>Dourbalya</i> (Exhaustion / Debility)	Can do routine exercise/work	0
		Can do moderate exercise with difficulty	1
		Can do mild exercise only, with difficulty	2
		Cannot do mild exercise too	3
5	<i>Mukha Talu Shosha</i> (Dryness of mouth)	No mukha talu shosha	0
		Occasionally dryness of oral cavity & disappear just after taking water	1
		Persistence dryness of mouth and subsides after taking more quantity of water	2
		Continuous dryness of mouth and does not subsides even after taking more quantity of water.	3
6	<i>Kara Pada Daha</i> (Burning sensation in palms and soles)	No daha	0
		Kara pada daha is not continuous	1
		Kara pada daha is continuous but not severe	2
		Kara pada daha is continuous and severe	3
7	<i>Kara Pada Suptata</i> (Numbness in palms and soles)	No suptata	0
		Kara pada suptata is not continuous	1
		Kara pada suptata is continuous but not severe	2
		Kara pada suptata is continuous and severe	3
8	<i>Shithilangata</i> (Fatigue)	No fatigue	0
		Fatigue on doing heavy work	1
		Fatigue on doing moderate work	2
		Fatigue on doing mild work	3

RESULTS

In TP group, it was seen that *Prabhoota Mootrata* was reduced by 25.94%, *Pipasadhikya* by 47.81%, *Kshuadhikya* by 73.35%, *Dourbalya* by 70%, *Mukhatalushosha* by 69.24%, *Karapadadaha* by 66.67%, *Karapadasuptata* by 53.84%, *Shareerabharahani* by 100% and *Shithilangata* by 80.65%. FBS was reduced by 16.91%, PPBS by 21.71%, FUS by 79.82% and PPUS by 87.46%.

In VR group it was seen that *Prabhoota Mootrata* was reduced by 34.62%, *Pipasadhikya* by 42.15%, *Kshudadhikya* by 82.34%, *Dourbalya* by 77.41%, *Mukhatalushosha* by 62.94%, *Karapadadaha* by 39.14%, *Karapadasuptata* by 51.73%, *Shareerabharahani* by 100% and

Shithilangata by 64.54%. FBS was reduced by 9.02%, PPBS by 15%, FUS by 49.85% and PPUS by 49.85%.

There was maximum remission in 13.33% of patients in TP group and 33.33% of patients in VR group, moderate remission in 73.33% of patients in TP group and 33.33% of patients in VR group. In TP group only 13.33% of patients had mild remission while in VR group 33.33% of patients had mild remission.

On overall assessment comparing the effect of both the formulations on individual parameters shows that *Triphaladi Kwatha* gave better relief in *Pipasaadhikya*, *Mukhatalushosha*, *Karapadadaha*, *Karapadasuptata*, *Shithilangatha*, FBS, PPBS, FUS and PPUS. *Vidangarajanyadi Kwatha* gave better relief in *Prabhoota Mootrata*, *Kshudaadhikya* and *Dourbalya*. Both the formulations gave equal relief in *Shareerabharahani*. Thus, difference in means showed that effect was better in TP group.

Comparing the effect of drugs showed no statistical significance in any parameters. This showed that effect by the two formulations is almost equal without any much difference statistically.

Table 2: Effect of treatment on subjective parameters.

Group	Mean		BT-AT	% of relief	SD		SEM		Median		Z	P
	BT	AT			BT	AT	BT	AT	BT	AT		
Prabhoota Mootrata												
TP Group	1.800	1.333	0.467	25.94	0.561	0.488	0.145	0.126	2	1	-2.646	0.016
VR Group	1.733	1.133	0.600	34.62	0.594	0.516	0.153	0.133	2	1	-2.714	0.008
Pipasa adhikya												
TP Group	1.533	0.800	0.733	47.81	0.516	0.414	0.133	0.107	2	1	-3.317	<0.001
VR Group	1.267	0.733	0.534	42.15	0.458	0.458	0.118	0.118	1	1	-2.828	0.008
Kshuda adhikya												
TP Group	2.000	0.533	1.467	73.35	0.655	0.516	0.169	0.133	2	1	-3.397	<0.001
VR Group	1.133	0.200	0.933	82.34	0.834	0.414	0.215	0.107	1	0	-2.889	0.002
Dourbalya												
TP Group	2.000	0.600	1.400	70	0.535	0.632	0.138	0.163	1	0	-3.520	<0.001
VR Group	2.067	0.467	1.6	77.41	0.458	0.640	0.118	0.165	2	0	-3.520	<0.001

<i>Mukha Talu Shosha</i>												
TP Group	1.733	0.533	1.2	69.24	0.594	0.516	0.153	0.133	2	1	- 3.286	<0.001
VR Group	1.800	0.667	1.133	62.94	0.516	0.488	0.145	0.126	2	1	- 3.494	<0.001
<i>Kara Pada Daha</i>												
TP Group	1.200	0.400	0.800	66.67	0.941	0.632	0.243	0.163	1	0	- 2.972	0.002
VR Group	1.533	0.933	0.600	39.14	1.060	0.884	0.274	0.228	2	1	- 2.460	0.016
<i>Kara Pada Suptata</i>												
TP Group	1.733	0.800	0.933	53.84	0.799	0.676	0.206	0.175	2	1	- 3.500	<0.001
VR Group	1.933	0.933	1.000	51.73	0.704	0.458	0.182	0.118	2	1	- 3.419	<0.001
<i>Shithilangata</i>												
TP Group	2.067	0.400	1.667	80.65	0.704	0.507	0.182	0.131	2	0	- 3.407	<0.001
VR Group	2.067	0.733	1.334	64.54	0.704	0.799	0.182	0.206	2	1	- 3.407	<0.001

Table 3: Effect of treatment on objective parameters.

Parameter	Group	Mean		BT-AT	% of relief	SD		SEM		t	P
		BT	AT			BT	AT	BT	AT		
FBS	TP Group	175.800	146.067	29.733	16.91	21.555	29.676	5.565	7.662	3.681	0.002
	VR Group	174.333	158.600	15.733	9.02	16.347	31.160	4.221	8.046	2.416	0.030
PPBS	TP Group	242.867	190.133	52.734	21.71	37.584	39.605	9.704	10.226	4.963	<0.001
	VR Group	246.333	209.400	36.933	15	21.124	43.664	5.454	11.274	3.245	0.006

Table 4: Comparison between the groups on subjective parameters.

Parameter	Group	Mean	SD	SEM	Median	U value	P value
<i>Prabhoota Mootrata</i>	TP Group	0.467	0.516	0.133	0	101.500	0.621
	VR Group	0.600	0.632	0.163	1		
<i>Pipasa adhikya</i>	TP Group	0.733	0.458	0.118	1	90.000	0.275
	VR Group	0.533	0.516	0.133	1		
<i>Kshuda adhikya</i>	TP Group	1.467	0.640	0.165	2	70.500	0.064
	VR Group	0.933	0.799	0.206	1		
<i>Dourbalya</i>	TP	1.400	0.507	0.131	1	90.000	0.292

	Group						
	VR Group	1.600	0.507	0.131	2		
<i>Mukha Talu Shosha</i>	TP Group	1.200	0.676	0.175	1	104.500	0.715
	VR Group	1.133	0.516	0.133	1		
<i>Kara Pada Daha</i>	TP Group	0.800	0.676	0.175	1	93.000	0.389
	VR Group	0.600	0.737	0.190	0		
<i>Kara Pada Suptata</i>	TP Group	0.933	0.458	0.118	1	106.000	0.736
	VR Group	1.000	0.535	0.138	1		
<i>Shithilangata</i>	TP Group	1.667	0.724	0.187	2	80.000	0.147
	VR Group	1.333	0.724	0.187	1		

Table 5: Comparison between the groups on objective parameters.

Parameter	Group	Mean		BT-AT	Difference in means	SD	SEM	t value	P value
		BT	AT						
FBS	TP Group	175.800	146.067	29.733	14	31.288	8.078	1.349	0.189
	VR Group	174.333	158.600	15.733		25.226	6.513		
PPBS	TP Group	242.867	190.133	52.734	15.801	41.152	10.625	1.015	0.319
	VR Group	246.333	209.400	36.933		44.075	11.380		

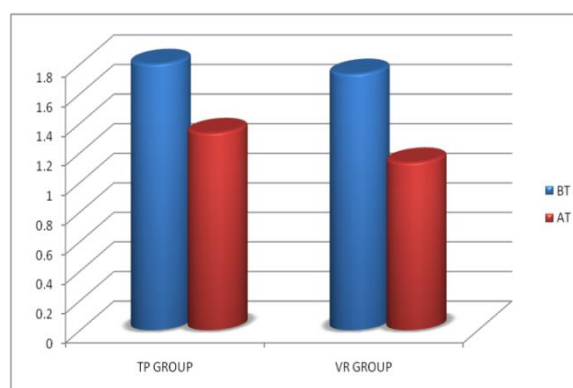


Figure 1: Effect of treatments on prabhoota mootrata.

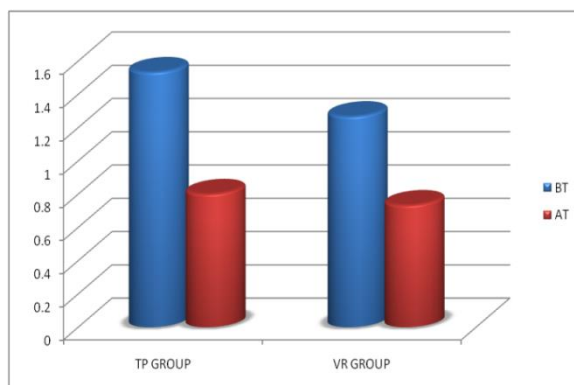


Figure 2: Effect of treatments on pipasa adhikya.

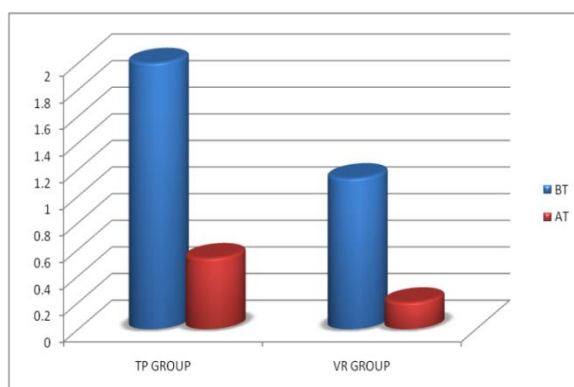


Figure 3: Effect of treatments on kshuda adhikya.

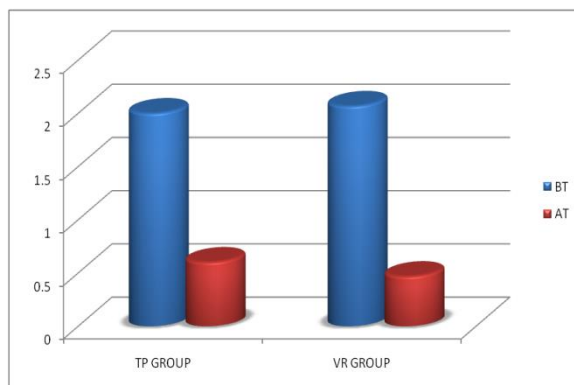


Figure 4: Effect of treatments on dourbalya.

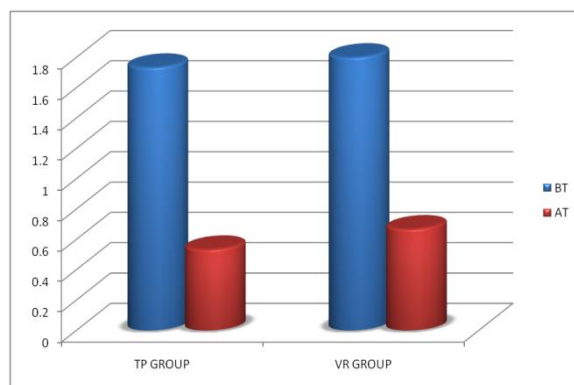


Figure 5: Effect of treatments on mukha talu shosha.

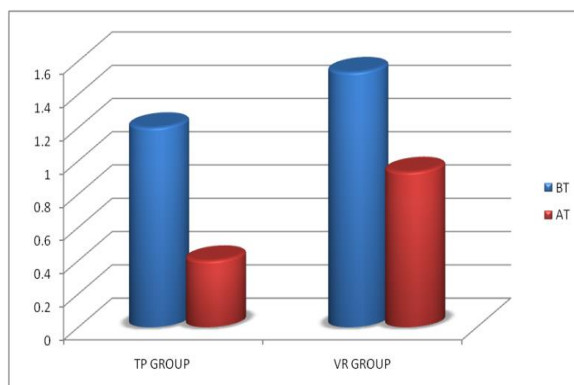


Figure 6: Effect of treatments on kara pada daha.

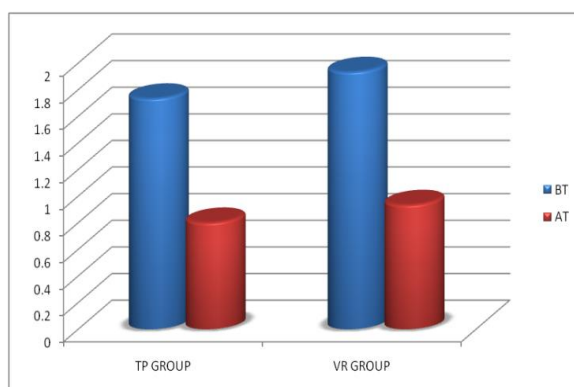


Figure 7: Effect of treatments on kara pada suptata.

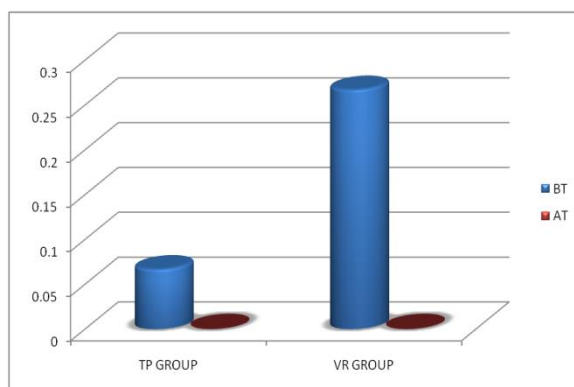


Figure 8: Effect of treatments on shareera bharahani.

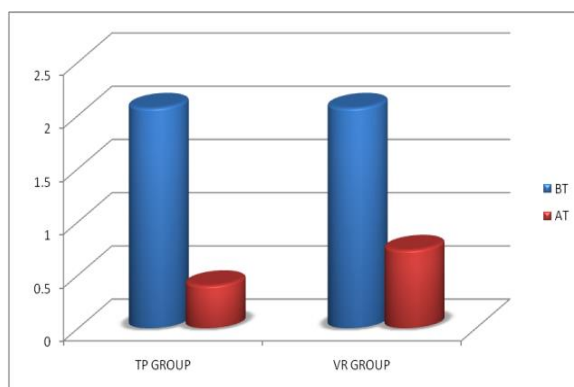


Figure 9: Effect of treatments on shithilangata.

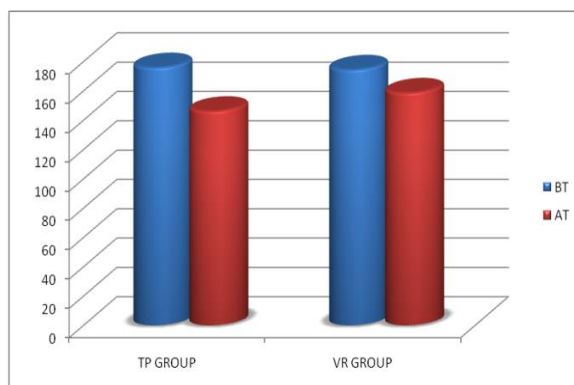


Figure 10: Effect of treatments on FBS Level.

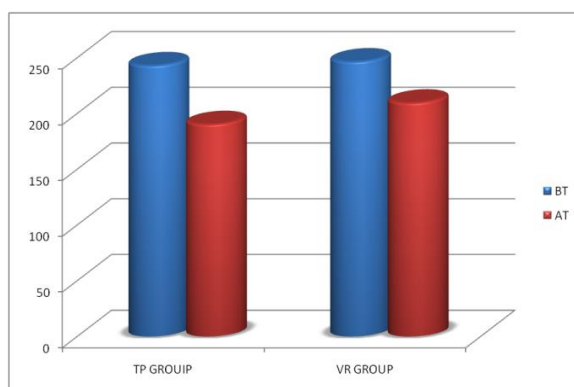


Figure 11: Effect of treatments on PPBS.

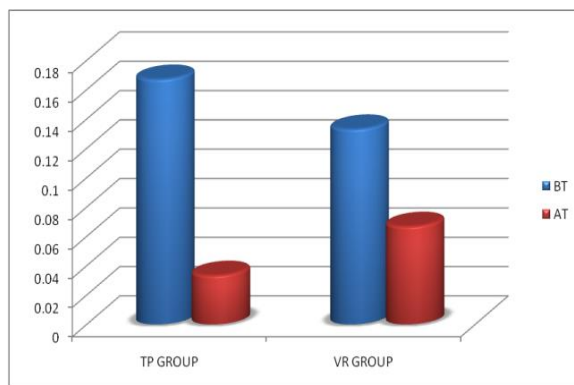


Figure 12: Effect of treatments on FUS.

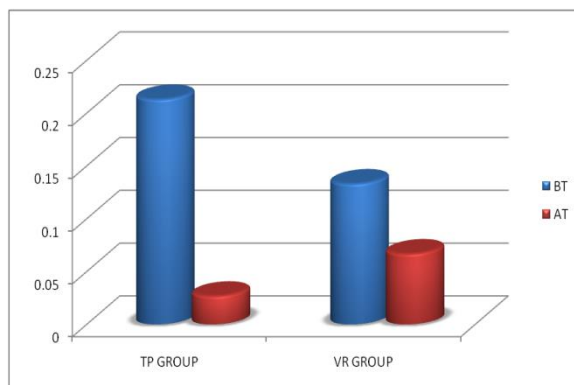


Figure 13: Effect of treatments on PPUS.

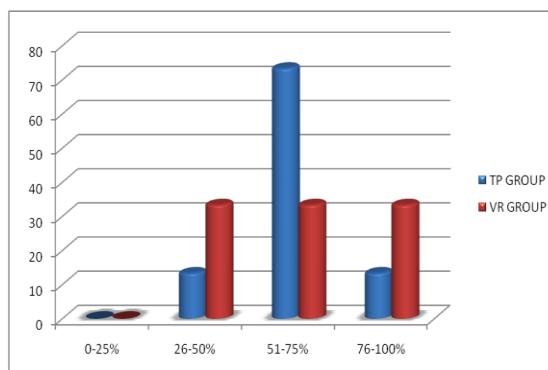


Figure 14: Overall assessment of subjective parameter in between groups.

DISCUSSION

Triphaladi Kwatha is mentioned in *Yogarathnakara* as an effective treatment in *Prameha* which contains *Triphala*, *Devadaru*, *Daruharidra* and *Mustha*. *Triphaladi Kwatha* acts as *Lekhaniya*, *Virechanopaga*, *Kaphahara* and *Medohara*. *Harithaki*, *Vibhitaki*, *Amalaki* and *Devadaru* present in this formulation have *Pramehaghna* action. *Amalaki*, *Vibhitaki* and *Mustha* have *Balya*, *Rasayana* and *Dhatuwardhaka* action, thus it helps in rejuvenation of the cells and rectify the *Khavaigunya* in the *Rogasthana*. *Triphala* is *Tridosahara* and it helps to rectify the *Doshadushti* and does the *Samprapti Vighatana*. *Kaphahara Karma* of all the six drugs removes the *Margavarana* by reducing *Kapha* and *Meda*, so it is helpful in *Avaranajanya Prameha* also. The *Ushna Virya* of *Harithaki*, *Vibhitaki* and *Daruharidra* results *Vata-Kaphaharana* and clears the *Samprapti*. *Triphala* and *Daruharidra* have *Chakshushya Guna*, so the complications of Diabetes like diabetic retinopathy if any present can be helped by this formulation. As this formulation has *Rechana Guna*, it helps in *Srotoshodhana* and in turn helps in *Sthoola* patients.

Vidangarajanyadi Kwatha is mentioned in *Yogarathnakara* in *Dusthara* (severe) *Prameha*, which contains *Vidanga*, *Haridra*, *Yashtimadhu*, *Nagara*, and *Gokshura*. It has *Vata-Kaphahara*, *Medohara*, *Lekhaniya* and *Mutra Virechaniya* effect. *Ushna Virya* of *Vidanga*, *Haridra* as well as *Nagara* and its *Vata-Kaphahara Karma* helps in both variety of *Prameha*. The *Vatahara Guna* of *Vidanga*, *Yashtimadhu* and *Nagara* reverses the *Vatadushti* responsible for *Prameha*. *Nadibalya Karma* of *Vidanga* and *Yashtimadhu* is useful in neuropathy, a condition which occurs as the complication of Diabetes. In addition to this *Dahahara* property of *Yashtimadhu* also helps in neuropathy condition. *Vidanga*, *Haridra* and *Gokshura* have *Rasayana* and *Balya Karma* which will rectify the *Khavaigunya* of the *Roga*. The *Tridoshashamaka Karma* of *Haridra* is useful in all types of *Prameha*. It also has *Mutrasangrahaniya Guna*. *Haridra* is considered as *Agrya Dravya* for *Prameha*.

CONCLUSION

This study showed that effect by the two formulations is almost equal without any much difference statistically. Comparing the effect of drugs showed no statistical significance in any parameters. The difference in means of individual parameters showed that effect was better in TP group than in VR group. After the study, with statistical evidence it can be conclude that, the *Triphaladi Kwatha* and *Vidangarajanyadi Kwatha* are ideal medicines for the patients suffering with *Prameha* / Diabetes Mellitus in reducing the clinical symptoms of the diseases as well as in reduction of hyperglycemia.

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