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A RANDOMIZED DOUBLE BLIND COMPARATIVE CLINICAL STUDY ON PHALATRIKADI KWATHA&VIDANGA RAJANYADI KWATHA IN MADHUMEHA (DIABETES MELLITUS)

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ABSTRACT

Objectives: To evaluate the therapeutic effect of *Phalatrikadikwatha* in *Madhumeha*. To evaluate the therapeutic effect of *VidangaRajanyadikwatha* in *Madhumeha*. Comparing the therapeutic effect of *Phalatrikadikwatha* and *VidangaRajanyadikwatha* in patients suffering from *Madhumeha.* **Design**: Study type- A randomized double blind comparative clinical study. **Setting**: S.D.M college of Ayurveda Hospital, Udupi; Participants: 30 patients of *Madhumeha* /Diabetes Mellitus having symptoms of *Madhumeha* (polyuria, polydypsia, and unexplained weight loss) plus casual plasma glucose concentration ≥200 mg/dl or fasting plasma glucose ≥126 mg/dl were randomly categorized into two groups. **Interventions**: In (Group A) - Selected patients were orally treated with *Phalatrikadikwatha* in a dose of 50ml BD before food for 28days and in (Group B) - Selected patients were orally treated with *vidangaRajanyadikwatha* in a dose of 50ml BD before food for 28 days follow up duration-30 days and total duration of study- 58 days **Objective Parameters**: Fasting blood sugar, Post prandial blood sugar, Fasting urine sugar, Post prandial urine sugar. **Subjective Parameters**: *Atibhubuksha, AtiMutrapravritti, AtiTrishna, Dourbalya, Mukhatalushosha, Kara padadaha, Kara padasuptata,* and *Shithilangata.* **Results**: The effect of *Phalatrikadikwatha* on individual parameters showed a better relief in *atibhubuksha, atitrishna, dourbalya, karapadasupta*, FBS, FUS &*Vidangarajanyadikwatha* gave better relief in *atimutrapravritti, mukhatalushosha, karapadadaha, shithilangata*, PPBS and PPUS. Comparing the effect of drugs showed a statistical significance in *atibhubuksha* parameter and no statistical significance in the rest of the parameters. **Conclusions:** Both the *kwatha* are ideal medicines in patients suffering from *Madhumeha* in reducing the symptoms and in reduction of hyperglycemia.

Keywords: *Madhumeha, Phalatrikadikwatha, VidangaRajanyadikwatha*.

INTRODUCTION

Madhumeha is a commonly occurring type of *Prameha*since ages. *Madhumeha* is a *Santarpana-janya Roga* and also included in *Ashtmahagadas*[1]. As the disease is chronic in nature it is also addressed as *Prameho Anushanginaam*[2].It involves all the three *Dosha* and ten *Dushya* that includes *Meda, Rakta, Shukra, Ambu, Vasa, Lasika, Majja, Rasa, Ojas* and *mamsa*[3]. The result of *aparipakva-kapha* formed due to indulgence of etiological factors with *meda* proceeds downward through the *Mutravaharotas* and gets settled at *bastimukha* leading to *prabhootamutrata,avilamutrata*etc symptoms. The etiology of the Diabetes Mellitus (DM), factors contributing to hyperglycemia includes reduced insulin secretion, decreased glucose utilization, and increased glucose production. The metabolic deregulation associated with DM causes secondary pathophysiologic changes in multiple organ systems that impose a tremendous burden on the individual with diabetes and on the health care system. Non-Insulin Dependent Diabetes Mellitus (NIDDM) has become the burning issue across the world in the near past. India leads the world with largest number of diabetic subjects earning the dubious distinction of being termed the diabetes capital of the world[4]

Globalization may be good for economy but it is a threat to civilization. So prevalence rate of type 2 Diabetes Mellitus correlates with the degree of modernization and many societies which are rapidly undergoing a transformation from traditional to modernization lifestyles are experiencing some of the highest rates of diabetes mellitus[5]. WHO concluded that the total number of people with DM is projected to rise from 171 million in 2000 to 366 million in 2030.India stands in the top most 3 countries having highest number of people with DM along with China & United States of America. The ultimate aim is a good control and management of *Madhumeha* and thus reducing the risk of the development of complications.

OBJECTIVES OF THE STUDY

- To evaluate the therapeutic effect of *Phalatrikadikwatha*[6]in*Madhumeha.*
- To evaluate the therapeutic effect of *Vidanga-Rajanyadi kwatha*[7]in *Madhumeha*.
- Comparing the therapeutic effect of *Phalatrikadikwatha* and *VidangaRajanyadikwatha* in patients suffering from *Madhumeha*

Source of data:

Minimum 30 Patients diagnosed as *Madhumeha* were taken for study from OPD and IPD of SDM Ayurveda Hospital, Udupi, Karnataka and *kwatha-choorna* was 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. A special proforma was prepared with all points of history taking, physical signs, symptoms as mentioned in Ayurveda and allied sciences. Accordingly, selected patients were subjected to detailed clinical history and complete physical examination.

Design of the study:

A randomized double blind comparative clinical study.

Intervention: 30 patients were randomly grouped into two groups of 15 each by using Permuted-Block randomization method. Patients who are already on other anti-diabetic drugs will also be taken in this study after discontinuing the treatment and after the wash out period of one week.

GROUP A – *Phalatrikadikwatha* group (PT group).
Selected patients were orally treated with *Phalatrikadikwatha* in a dose of 50ml BD before food for 28days.
GROUP B – *VidangaRajanyadikwatha* group (VR group).
Selected patients were orally treated with *vidangaRajanyadikwatha* in a dose of 50ml BD before food for 28 days.
Follow up duration-30 days
Total duration of study- 58 days

Diagnostic criteria[8]:
Patients fulfilling the following criteria:
1. Fasting Plasma Glucose ≥126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 Hours
2. Two-hour plasma glucose ≥ 200mg/dl, with or without the association of
3. Symptoms of *Madhumeha* like *prabhootamutra, Avila mutrata, kshut* and *pipasaadhikya*

Inclusion criteria:
1. Patients fulfilling the diagnostic criteria
2. Patients between the age group of 30 to 70 years of either sex.
3. Fasting Plasma Glucose Level ≤ 200 mg/dl or
4. Post Prandial Plasma Glucose level≤ 350 mg/dl

Exclusion criteria:
1. Type 1 DM.
2. Diabetic Cardiomyopathy, Neuropathy, Nephropathy, Retinopathy,
3. Diabetic ketoacidosis
4. CNS disorders e.g. Encephalopathy
5. Cardiovascular disease, CKD, Gastrointestinal disease
6. Pregnant & Lactating women.
7. 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 0 day, 28th day and 58th day.[Table no.1]

Subjective Parameters:
Atibhubuksha, AtiMutrapravritti, AtiTrishna, Dourbalya, Mukhatalushosha, Karapadadaha, Karapadasuptata, Shithilangata.

Objective Parameters: It includes estimation of- Fasting Plasma Glucose Level, Post Prandial Plasma Glucose Level, Fasting urine sugar level, and Post Prandial urine sugar level. Before and at the end of the therapy on 28th day.

Statistical test - Statistical analysis was done based on Sigma Stat Statistics software version 3.5. In this study Wilcoxon signed rank test was taken in place of paired t test when data is ordinal data, where distribution is not normal or small sample size. Paired t test is used when data is numerical. In between group analysis, Mann Whitney test is used for ordinal data, where distribution is not normal or small sample size. When data is numerical unpaired t test is used. These tests are selected as this study is conducted on 2 groups

Results
In PT Group It was seen that *Atibhubuksha* was reduced by 87%, *Atimutrapravritti*by 83.3%, *Atitrishna* by 93.3%, *daurbalya* by 91.6%, and *shithilangata* by 70%. FBS was reduced by 28.04%, and PPBS was reduced 29.69%.FUS by 99.9%, and PPUS by 100% In VR Group It was seen that *Atibhubuksha* was reduced by 58%, *Atimutraparvritti* by 58%, *AtiTrishna* by 61.6%, *daurbalya* by

72.7%, *shithilangata* by 69.2%.FBS was reduced by 36% and PPBS was reduced by 35.22%. FUS by 83.8%, and PPUS by 100% .The effect of the formulation on individual parameters shows that PT *kwatha* gave a better relief in *atibhubuksha, atitrishna, dourbalya, karapadasupta*, FBS,FUS & in quality of life. VR group gave better relief in *atimutrapravritti, mukhatalushosha, karapadadaha, shithilangata*, PPBS and PPUS. Thus difference in means showed that effect was better in PT group.

Comparing the effect of drugs showed a statistical significance in *atibhubuksha* parameter and no statistical significance in the rest parameters. This showed that the effect by the formulation is almost equal without any much difference statistically.

[Table no.2,3,4,5.]

DISCUSSION

Phalatrikadikwatha is mentioned in *charakasamhita* as an effective treatment in *Prameha*.The formulation *Phalatrikadikwatha* consists of *Amalaki, Hareetaki, Bibheetaki, Daruharidra, Indravaruni* and *Musta*. *Phalatrikadikwatha* acts as *lekhaniya, kaphahara* & *medohara*. *Amalaki* and *Indravaruni* present in the formulation have a *premehaghna* property. *Amalaki, Musta* and *Bibhitaki* have *balya, rasayana* and *dhatuvardhaka* property, thus helps in rejuvenation of the cells and rectifying the *khavaigunya* in the *rogadhisthaana. Amalaki, Hareetaki, Bibheetaki* present in the formulation is *tridoshahara* and help in rectifying *doshadushti*and thus helps in *sampraptivighatana*. The *kaphahara* property of all the above 6 drugs, help in *kaphamedaharana* and thus helps in removing *margavarana,* thus helps in the *avaranaja* variety. *Amalaki, Hareetaki, Bibheetaki, Daruharidra* have *rukshaguna* thus is *kapha, medohara* helping in the *sampraptivightana*. *Hareetaki, Bibheetaki, Daruharidra, Indravaruni* have *ushnaviryaand* thus helps in *vatakaphaharana* and reversal of *samprapti*. *Haritaki* and *daruharidra* have *chakshushya* property. The complications of diabetes like retinopathy, if any present can be helped by the formulation. *Indravaruni* has a *rechaka* property, thus helping in the *srotoshodhana* and in turn helpful in *sthula* patients[9, 10, 11,12,13,14.]

VidangaRajanyadikwatha is mentioned in *Sahasrayoga* in *dustharaPrameha,* has *vatakaphahara,medohara, lekhaniya* and *mutravirecaniya.* The formulation *Vidangarajanyadikwatha* consists of *Vidanga, Haridra, Yastimadhu, Shunti* and *Gokshura* taken in equal parts. *Vidanga, Haridra* and *Shunti* have *ushnavirya* and thus *vatakaphahara* effect thus helping in both the varieties of *prameha. Vidanga, Yastimadhu* and *Shunti* have *vatahara*effect and thus reverse the *vatadushti* responsible for the disease. *Vidanga* and *Yashti* have *nadibalya* effect and thus useful when there is neuropathy as a complication of diabetes. *Yastimadhu* has a *dahahara* property necessary to act on the neuropathy condition. *Vidanga, Haridra* and *Gokshura* have *rasayana* and *balya* property necessary for the rectification of the *khavaigunya* in the disease. *Haridra* has a *tridoshashamaka* effect useful in all varieties of *Prameha. Haridra* also has a *mutrasangrahaniya* quality. *Haridra* is considered to be the best *agryadravya* in *prameha.*[15, 16,17,18,19.]

CONCLUSION

This study showed that the effect by the two formulations is almost equal without any much difference statistically. The difference in means of the individual parameters showed that effect was better in PT group than in VR group.

Table 1: Grading of assessment parameters -

S.no	Criteria	Details	Score
1	*Atibhubuksha* (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
2	*AtiMutrapravritti* (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
3	*AtiTrishna* (Polydypsia) Quantity of water intake Polydipsia	Intake of water 5 – 7 times/24 hours with quantity 1.5– 2.5 Liter/24 hours1	0
		Intake of water 7 - 9 times/24 hours with quantity 2.5- 3.0 Litre/24 hours	1
		Intake of water 9 – 11 times/24 hours with quantity 3.0- 3.5 Liter/24 hours	2
		Intake of water >11 times/24 hours with quantity >3.5 litre/24 Hours	3
4	*Kara-Pada-Tala-Daha* (Neuropathy)	No *Daha*	0
		Kara-pada-tala-daha is not continuous	1
		Kara-pada-tala-daha continuous but not severe	2
		*Kara-pada-tala-daha*continuous and severe	3
5	*Kara-Pada-Tala-Supti*(Neuropathy)	No *supti*	0
		*Kara-pada-tala-Supti*is not continuous	1
		Kara-pada-tala-Supti continuous but not sever	2
		Kara-pada-tala-Supti continuous and severe	3
6	*Daurbalya*	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
7	*Mukhataalushosha*	No *mukhataalushosha*	0
		Occasionally dryness of oral cavity & disappear just after taking water	1
		Persistence of dryness of mouth & subsides after taking more quantity of water	2
		Continuous dryness of mouth& does not subsides even after taking more quantity of water	3
8	*Shithilangata*	No Fatigue	0
		Fatigue on doing heavy work	1
		Fatigue on doing moderate work	2
		Fatigue on doing mild work	3

Table 2: Effect on treatment on subjective parameters

Parameters	Group	Mean		BT-AT	% relief	SD		SEM		Median		Z	P
		BT (±SD)	AT (±SD)			BT	AT	BT	AT	BT	AT		
Atibhubuksh	PT group	2.067 (±0.884)	0.267 (±0.458)	1.800	87%	0.884	0.458	0.228	0.118	2.067	0.267	-3.402	<0.001
	VR group	1.933 (±0.799)	0.800 (±0.414)	1.133	58%	0.799	0.414	0.206	0.107	1.933	0.800	-3.314	<0.001
AtiMutra-pravritti	PT group	1.200 (±1.082)	0.200 (±0.414)	1.000	83.3 %	1.082	0.414	0.279	0.107	1.200	2.000	-2.877	<0.002
	VR group	1.933 (±0.799)	0.800 (±0.414)	1.133	58%	0.884	0.488	0.279	0.126	3.000	1.000	-3.358	<0.001
AtiTrishna	PT group	2.000 (±2.420)	0.133 (±0.352)	1.867	93.3 %	2.420	0.352	0.625	0.090	2.000	1.000	-3.108	<0.001
	VR group	1.733 (±0.884)	0.667 (±0.488)	1.067	61.6 %	1.187	0.516	0.307	0.133	2.000	0.00	-3.017	<0.001
Dourbalya	PT group	1.600 (±0.910)	0.133 (±0.352)	1.467	91.6 %	0.910	0.352	0.235	0.090	2.000	0.00	-3.169	<0.001
	VR group	1.467 (±1.125)	0.400 (±0.507)	1.067	72.7 %	1.125	0.507	0.291	0.131	2.000	0.00	-3.017	<0.001

Table 3: Effect on treatment on objective parameters

PARAMETER	Group	MEAN SCORE		DIFFERENCE IN MEAN	PAIRED 't' test			
		BT(±SE)	AT(±SE)		S.D	S.E.M.	't'	P
FBS	PT group	162.667 (±30.807)	117.067 (±12.859)	45.6	21.777	5.632	8.110	<0.001
	VR group	158.000 (±23.391)	122.067 (±16.884)	36	16.538	4.270	8.415	<0.001
PPBS	PT group	259.067 (±44.467)	182.133 (±42.382)	76.934	22.382	5.779	13.313	<0.001
	VR group	264.000 (±36.432)	171.067 (±52.436)	93.00	58.752	15.170	6.126	<0.001
FUS	PT	0.427	0.00667	0.4204	1.324	0.342	2.107	<0.016

	group	(±0.587)	(±0.0258)					
	VR group	0.453 (±0.693)	0.0733 (±0.258)	0.3797	0.573	0.148	2.566	<0.022
PPUS	PT group	0.440 (±0.514)	0.000 (±0.000)	0.440	1.514	0.133	3.317	<0.005
	VR group	0.693 (±0.557)	0.000 (±0.000)	0.693	0.557	0.144	4.818	<0.001

Table 4: Comparisonbetween the groupson subjective parameters

Parameters	Group	Mean	S.D	SEM	Median	U	P
Atibhubuksha	PT group	1.800	0.775	0.200	3.000	167.500	0.014
	VR group	1.133	0.640	0.165	1.000		
Atimutrapravritti	PT group	1.000	0.926	0.239	3.000	102.500	0.665
	VR group	1.133	0.067	0.594	1.000		
Atitrishna	PT group	1.867	2.446	0.631	1.000	130.500	0.445
	VR group	1.067	0.799	0.206	1.000		
Dourbalya	PT group	1.467	0.915	0.236	3.000	142.00	0.200
	VR group	1.067	0.799	0.206	1.000		

Table 5: Comparison between the groupson objective parameters

Parameters	Group	Mean		BT-AT	Difference in means	Unpaired 't' Test			
		BT	AT			S.D	S.E.M	't'	P
FBS	PT Group	162.667	117.067	45.6	9.6	21.777	5.623	1.369	0.182
	VR Group	158.000	122.067	36		16.538	4.270		
PPBS	PTGroup	259.067	182.133	76.934	16.00	22.381	5.779	0.986	0.333
	VRGroup	264.000	171.067	93.00		52.752	5.170		
FUS	PTGroup	0.427	0.00667	0.4204	0.0407	1.324	0.34	0.913	0.369
	VRGroup	0.453	0.0733	0.3797		0.573	0.148		
PPUS	PTGroup	0.440	0.000	0.440	0.253	0.514	0.133	1.294	0.294
	VR Group	0.693	0.000	0.693		0.693	0.144		

Figure 1: Effect of Treatment on *Atibhubuksha*

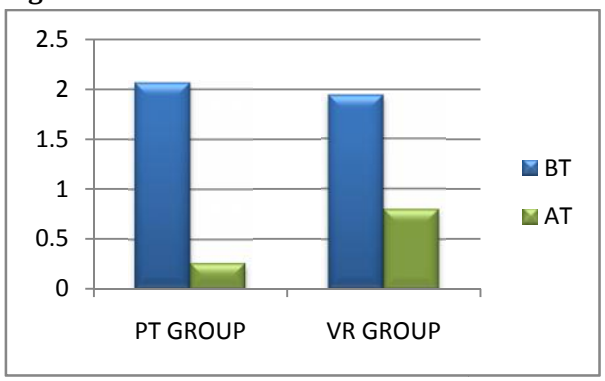


Figure 2: Effect of Treatment on *AtiMutrapravrit-ti*

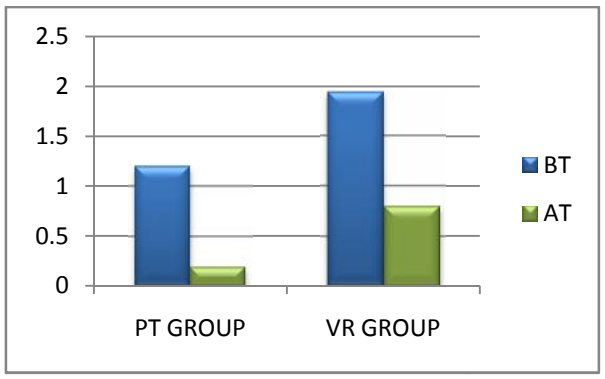


Figure 3: Effect of Treatment on *AtiTrishna*

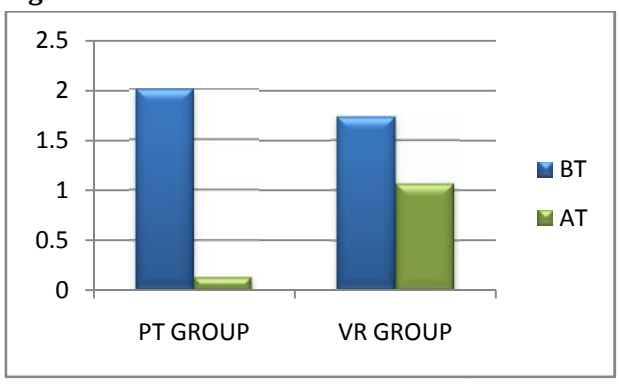


Figure 4: Effect of Treatment on *Dourbalya*

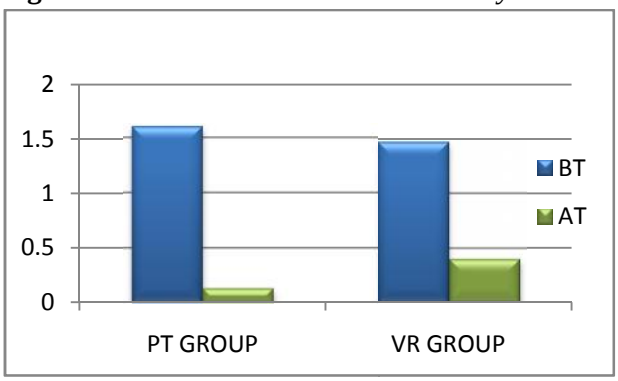


Figure 5: Effect of Treatment on FBS

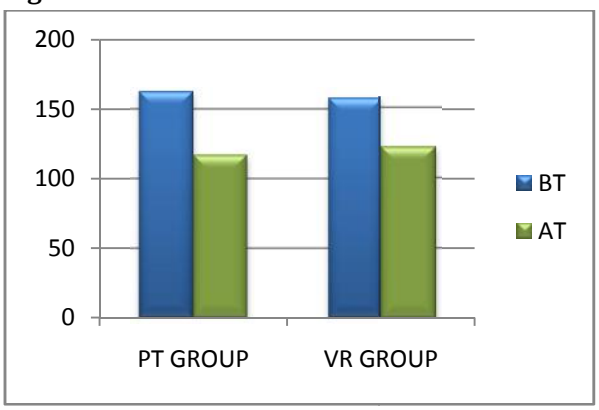


Figure 6: Effect of Treatment on PPBS

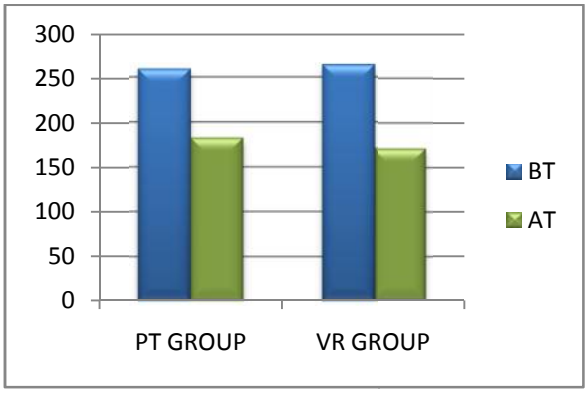


Figure 7: Effect of Treatment on FUS

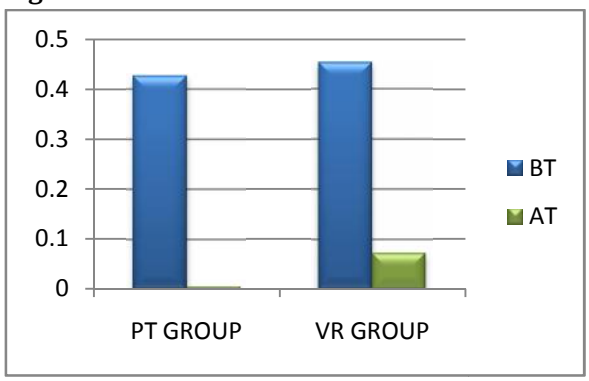
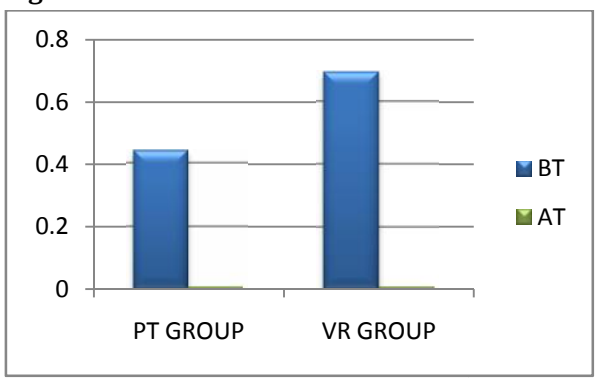


Figure 8: Effect of Treatment on PPUS



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