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ISSN: 2278-4772

Ayurpharm Int J Ayur Alli Sci., Vol. 6, No. 9 (2017) Pages 181 – 187

Research Article

EFFICACY OF VIDANGA RAJANYADI KASHAYA AND NISHAMALAKI CHURNA IN THE MANAGEMENT OF PRAMEHA W.S.R TO NIDDM: A CLINICAL TRIAL

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Received: 08-09-2017; Revised: 22-09-2017; Accepted: 27-09-2017

Abstract

Prameha is the disease afflicting mankind since a very long time and is one among Astamahagadas. Due to nidana sevana, it results in aparipakva Kapha and Meda;which inturn vitiates kleda and medhodharakala and leads to doshadusyasamoorchana. Kleda remaining after dhatvagnipaka does Adhomargagamana through the Mootravahasrotas and get localised at Bastimukha and leading to symptoms like Prabhootamutra, Aavilamutra etc. The present study intended to compare and ascertain the efficacy of Vidanga rajanyadi kashaya with Nishamalaki in treatment of Prameha w.s.r to NIDDM.A minimum of 30 patients were selected after thorough history taking, clinical assessment and laboratory investigations.15 patients are placed in each group. Group A: Vidanga rajanyadi kashaya will be given 50ml twice daily half an hour before food for 30 days. Group B: Nishamalaki churna will be given, 6 gm twice daily half an hour before food for 30 days with ushnajala as anupana. The present study was carried out on 30 patients of Prameha who were divided into 15 patients of either sex in each group A and B,who attended the OPD and IPD sections of Muniyal Institute of Ayurveda medical sciences, Manipal where Group A was treated with Vidangarajanyadi kashaya and Group B treated with Nishamalaki churna. Single blind randomized comparative clinical study was done with paired and unpaired t test. Moderate improvement is seen in the patients of Prameha after the treatment.The treatment reduces the subjective & objective Parameters that includes Polyuria, Polydypsia, FBS, PPBS and the parameter Urine sugar has no effect. Group A treated with Vidangarajanyadi kashaya showed better results than Group B treated with Nishamalaki churna.

Key words: Prameha; Diabetes mellitus; Vidanga rajanyadi kashaya; Nishamalaki churna.

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Cite This Article

Sija MU, Shripathi Acharya, Pramod Katti, Naveen K. Efficacy of Vidanga rajanyadi kashaya and Nishamalaki churna in the management of Prameha w.s.r to NIDDM: A clinical trial. Ayurpharm Int J Ayur Alli Sci. 2017;6(9):181-187.

www.ayurpharm.com
ISSN: 2278-4772
Ayurpharm Int J Ayur Alli Sci., Vol. 6, No. 9 (2017) Pages 181 – 187

INTRODUCTION

Prameha is not mentioned as such in Vedas, the description of a disease known as Asrava along with its treatment has been mentioned during Vedic era in Atharvaveda.[1] The English translator Whitney interpreted it as flux and Griffith as morbid flow, while Leman translated the meaning of asrava as Diabetes Mellitus.[2]

Prameha could be correlated with Non Insulin Dependent Diabetes Mellitus (NIDDM).The features exhibited in prameha and NIDDM were similar.

Diabetes Mellitus is a metabolic disorder in which the body is unable to produce enough insulin and not able to utilize it properly. It causes disturbances in carbohydrate, protein,lipid metabolism & complications such as retinopathy, microangiopathy & neuropathy. Diabetes Mellitus is a metabolic disorder which is seen commonly affecting the middle and old aged people. Sedentary lifestyle, Over eating and lack of exercise leads to this disorder.

MATERIAL AND METHODS

The present study was carried out on 30 patients who attended the OPD & IPD sections of Muniyal Institute of Ayurveda medical sciences, Manipal.

Inclusion criteria

1. Patients of either sex
2. Freshly diagnosed cases of Diabetes
3. Patients with age above 30 years and below 60 years.

Exclusion criteria

1. Patient with Insulin dependent Diabetes mellitus or severe grade blood glucose levels.
2. Patient with complications like diabetic ketoacidosis.

Though tremendous advancement in modern medicine in the form of oral hypoglycaemic agents and Insulin injections, absence of an ideal drug which has zero side effects and rejuvenative properties prevails. With this background there is a need for drugs from herbal source which is effective, cheap, easily available, and palatable that patients can use the drug lifelong to control Diabetes mellitus. This study focuses on assessing and comparing the effect of Vidanga rajanyadi kashaya[3] and Nishamalaki churna[4] in Prameha w.s.r to NIDDM.

Vidangarajanyadi is Kaphapittahara (Alleviates pittadosha and Kaphadosha) and Srothoshodhana in action. Nisha (*Curcuma longa*) is considered to be Agraoushadha (Drug of choice) in Prameha. Nishamalaki is Vatakaphahara (Alleviates Vata dosha and Kapha dosha) Rasayana (Rejuvinative) due to its properties. Hence this study is planned to find the individual efficacy of the above formulations and compare their effects in Prameha w.s.r to NIDDM.

3. Gestational diabetes will be excluded from the study
4. Multisystem involved diabetic patients.

Assessment criteria

a) Clinical parameters
Prabhutamutrata:[5] (Polyuria)
Pipasa[6] (Polydypsia)
b) Hematological parameters[7]
FBS (mg/dl)
PPBS (mg/dl)
Urine sugar (%)

Assessment of the parameters was made by scoring pattern as mentioned in Table 1.

Methods

- A minimum of 30 patients fulfilling the diagnostic and inclusion criteria

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Ayurpharm Int J Ayur Alli Sci., Vol. 6, No. 9 (2017) Pages 181 – 187

- Irrespective of their gender, caste, religion, education status and socio-economic status will be taken for the study.
- Registered patient will be allotted randomly by lottery method into two equal groups of minimum 15 patients each as A and B

Study design

Single blind randomized comparative clinical study. Statistical test adopted was Paired and Unpaired 't' test. Institutional ethical committee clearance number: IEC/KC/SJA/01.

RESULTS

In Group A, Prabhuthamutrata (quantity) ($p < 0.0001$) showed very significant value. The mean score of quantity of urine in 30 patients was 2.400 before the treatment which came down to 1.533 after the treatment got over. Statistical analysis showed t value of 9.539 & p value <0.0001 which is statically significant change.

In Group B, Prabhuthamutrata (quantity) ($p < 0.0086$) showed very significant value.The mean score of quantity of urine in 30 patients was 2.46 before the treatment which came down to 2.067 after the treatment got over. Statistical analysis showed t value of 3.055 & p value <0.0086 which is statically significant change.

In Group A, Trishna ($p<0.0001$) showed extremely significant value. The mean score of Trishna in 30 patients was 1.4000 before the treatment which came down to 0.4000 after the treatment got over. Statistical analysis showed t value of 14.500 & p value <0.0001 which is statically significant change.

In Group B, the mean score of Trishna in 30 patients was 1.067 before the treatment which came down to 0.6667 after the treatment got over. Statistical analysis showed t value of 3.055 & p value <0.0086 which is statically significant change. Trishna ($p<0.0086$) showed very significant value.

In Group A, the mean score of FBS in 30 patients was 2.200 before the treatment which came down to 1.400 after the treatment got over. Statistical analysis showed t value of 7.483 & p value <0.0001 which is statically significant change

In Group B, the mean score of FBS in 30 patients was 2.267 before the treatment which came down to 1.467 after the treatment got over. Statistical analysis showed t value of 7.483 & p value <0.0001 which is statically significant change.

In Group A, the mean score of PPBS in 30 patients was 2.067 before the treatment which came down to 1.267 after the treatment got over. Statistical analysis showed t value of 7.483 & p value <0.0001 which is statically significant change.

In Group B, the mean score of PPBS in 30 patients was 2.200 before the treatment which came down to 1.467 after the treatment got over. Statistical analysis showed t value of 6.205 & p value <0.0001 which is statically significant change

In Group A, the mean score of FUS in 30 patients in group was 1.000 before the treatment which came down to 0.1333 after the treatment got over. Statistical analysis showed t value of 9.539 & p value <0.0001 which is statically significant change. FUS ($p<0.0001$) showed statistically very significant value.

In Group B, the mean score of FUS in 30 patients was 2.533 before the treatment which came down to 1.133 after the treatment got over. Statistical analysis showed t value of 3.055 & p value <0.0086 which is statically

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ISSN: 2278-4772
Ayurpharm Int J Ayur Alli Sci., Vol. 6, No. 9 (2017) Pages 181 – 187

significant change. FUS ($p<0.0086$) showed statistically insignificant value. (Table 1)

Analysis of this data shows the results are statistically very significant between the two groups. (Table 2)

Definite improvements were seen in the patients of Prameha after the treatment. The treatment with Vidangarajanyadi kashaya and Nishamalaki churna helped in the reduction of symptoms like Polyuria, Polydypsia, FBS, PPBS. Anyhow the treatment had no effect on urine sugar. In comparison with Vidangarajanyadi kashaya and Nishamalaki churna,Vidangarajanyadi kashaya showed better results than Nishamalaki churna. (Graph 1 and Graph 2)

DISCUSSION

The management of Prameha is explained on the basis of Prameha patients i.e.Sthula Prameha & Krusha Prameha.[8] The line of treatments are Nidana parivarjana, Apakarshana Chikitsa in Margavarana janya Prameha, prakruthi vighatana chikitsa in Dhatu kshaya janya Prameha, Avastha Anusara chikitsa for Krusha & Durbala Pramehi. Apatarpana chikitsa for Sthula and Balavan prameha & a lot of shamana prayogas are mentioned in the literature. Samshamana chikitsa includes mainly deepana, Pachana, Kshut, Trit, Vyayama, Atapa, (having exposed to sun) & Maruta (exposing oneself to wind). According to the conditions of vitiated doshas & dushyas, vaidya has to suggest proper shamana chikitsa to the patient. Acharya Charaka & Vagbhatta says that the churna yoga's should be given to Vatika mehas. As nisha is the agraushadi for Prameha,[9] which will help in the rejuvenation of destructed pancreatic cells responsible for the production of Insulin.

Ahara viharas (Concomitant diet and Regimen): plays an important role in balancing the calorie intake and usage in the diabetic patients. Sugar, carbohydrate diet should be limited. Patient is advised to consume high fiber diet, leafy and raw vegetables, moderate milk and milk products. Moderate exercise, 15 minutes walk.

Different eatables prepared of yava should be given to the patient to eat. Persons habitually taking Amalaki (*Emblica officinalis*), haridra (*Curcuma longa*), yava (*Hordeum vulgare*), mudga (*Vigna radiate*), do not suffer from Prameha.[10]

Mode of action of Drug

In Prameha samprapthi, the main doshas are kapha & pitta, whereas the most important Dushyas are Meda and Kleda. So for the management of Prameha, such drugs have to be selected which are against Meda and Kleda. Vidangarajanyadi kashaya is having reference in Sahasrayogam & Nishamalaki churnam is having reference in Ashtanga hrudayam. The ingredients of both the formulations were having kaphahara properties and as the Prameha is a Kapha pradana vyadhi these formulations were useful in the disease. The above mentioned formulations of Vidangarajanyadi & Nishamalaki are having the property of Mootrasangrahana (Retention of urine) action which helps in the reduction of the symptom Prabhoothamootratha, which is considered as the cardinal feature of the disease Prameha.[11]

Agraushadi for Prameha is Nisha, which is having lekhana, vrishya, Kaphamedohara, tridhoshashamaka etc properties, has indeed got specific action against Hyperglycaemia and Hypercholesterolemia. Vidangarajanyadi is having the action of lekhana, so these together will be helpful in the patients of Prameha who were mentioned as Sthulapramehi. Most of the ingredients in both the formulations were having the properties like Rakthaprasadana, Kushtahara and Vranaropana etc which were helpful for the skin lesions which are produced in the disease Prameha.

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Table 1: Assessment criteria with Scoring

Sl.No.	Symptoms	Criteria	Scoring
1	Prabhootha mutratha (in liters)	1.5 – 2.0	0
		2.0 – 2.5	1
		2.5 – 3.0	2
		3.0 onwards	3
2	Pipasa (Polydypsia)	Feeling of thirst 7- 9 times/24 hours, either/or Intake of water 5- 7 times/24 hours with quantity 1.5-2.0 liter/24 hours	0
		Feeling of thirst 9 – 11 times/24 hours, either/or Intake of water 7 – 9 times/24 hours with quantity 2.0 -2.50 liter/24 hours-1	1
		Feeling of thirst 11-13 times/24 hours, either/or Intake of water 9-11 times/24 hours with quantity 2.50 -3.00 liter/24 hours -2	2
		Feeling of thirst >13 times/24 hours, either /or Intake of water >11 times/24 hours with quantity >3.00 liter/24 hours -3	3
3	FBS	Below 110 mg/dl	0
		110-170 mg/dl	1
		171-220 mg/dl	2
		Above 220 mg/dl	3
4	PPBS	Below 181 mg/dl	0
		181-230 mg/dl	1
		231-280 mg/dl	2
		Above 280mg/dl	3
5	FUS	Absence of Glucose in urine	0
		<0.5% Glucose in urine	1
		0.05 – 1.0% of Glucose in urine	2
		1.0 -2.0% of Glucose in urine	3
		>2.0% Glucose in urine	4

Table 2: Effect of treatments

Symptoms	Group	Mean		(%)	SD	SE	"t" value	"P" value
		BT	AT					
Prabhuthamutrata (Quantity)	A	2.400	1.533	40	0.3519	0.09085	9.539	<0.0001
	B	2.467	2.067	30	0.5071	0.1309	3.055	<0.0086
Trishna	A	1.4000	0.4000	61.53	0.2582	00.0667	7.500	<0.0001
	B	1.067	0.6667	47.5	0.5071	0.1309	3.055	<0.0086
FBS	A	2.200	1.400	36.4	0.4140	0.1069	7.483	<0.0001
	B	2.267	1.467	35.3	0.4140	0.1069	7.483	<0.0001
PPBS	A	2.067	1.267	38.7	0.4140	0.1069	7.483	<0.0001
	B	2.200	1.467	33	0.4577	0.1182	6.205	<0.0001
FUS	A	1.000	0.1333	86.7	0.3519	0.09085	9.539	<0.0001
	B	2.533	1.133	80.8	0.5071	0.1309	3.055	<0.0086

Table 3: Comparison between two groups

Symptoms	Mean score Group A			Mean score Group B			Unpaired t-value	p-value
	BT	AT	%	BT	AT	%		
Prabhoothamutrata	2.467	2.067	40	2.400	1.033	30	2.928	<0.0067
Trishna	1.4000	0.4000	61.53	1.067	0.6667	47.5	3.630	<0.0011
FBS	2.200	1.400	36.4	2.267	1.467	35.3	2.928	<0.0067
PPBS	2.067	1.267	38.7	2.200	1.467	33	0.000	<0.9999
FUS	1.000	0.133	86.7	2.533	1.133	80.8	2.928	<0.0067

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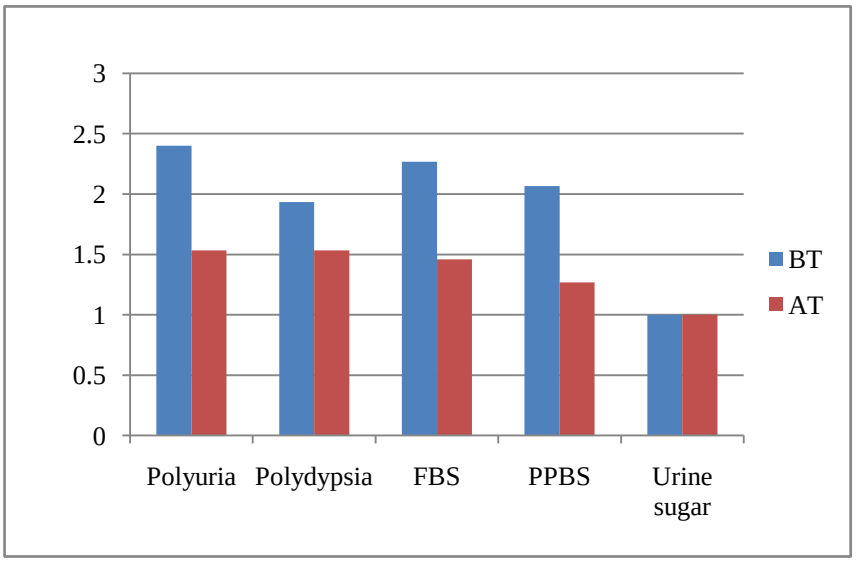
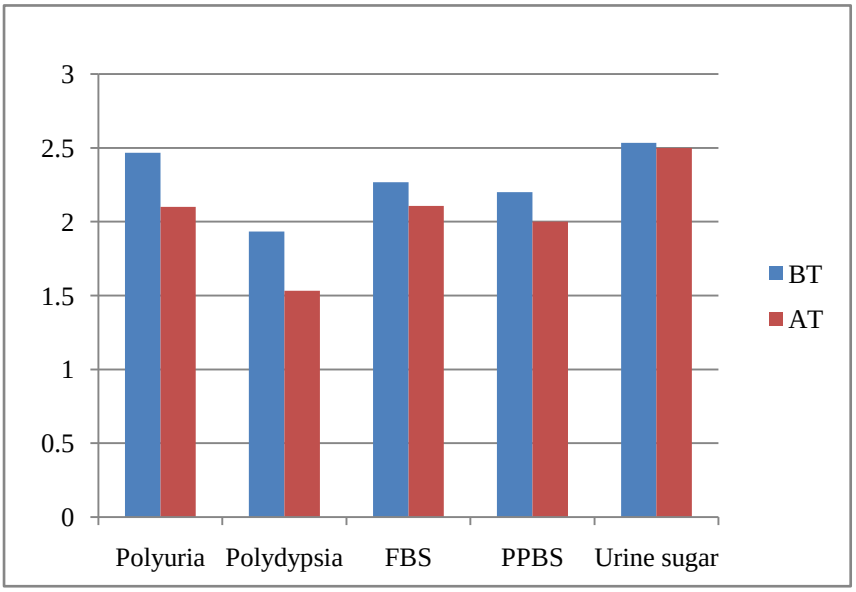
ISSN: 2278-4772
Ayurpharm Int J Ayur Alli Sci., Vol. 6, No. 9 (2017) Pages 181 – 187

Graph 1 Effect of Vidangarajanyadi kashaya in Group A



Graph 2: Effect of Nishamalaki churna in Group B



Particularly the drug Amalaki is having the Rasayana and Chakshusya properties because of which it will be helpful in the Prameha patients who will be having the symptoms of Daurbalya. Even the Chakshusya property will be helpful for the diabetic patients to avoid the complications like Diabetic Retinopathy[12] etc.

With this view a study entitled "A Comparative clinical study on the effect of Vidanga rajanyadi kashaya and Nishamalaki churna in Prameha" was framed in search of a safe and effective remedy in Ayurveda.

Observing the scores given to the individual symptoms and tests before & after the treatment in the 30 patients the results is statistically analyzed and the effect is discussed below.

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Subjective parameters

The mean score of Polyuria in 30 patients was 2.400 before the treatment which came down to 1.533 after the treatment got over in Group A & in Group B 30 patients was 2.467 before the treatment which came down to 2.067 after the treatment got over.

The present study shows 40% relief in group A and 30 % relief in group B. The mean score of Polydypsia in 30 patients in group A was 1.4000 before the treatment which came down to 0.4000 after the treatment got over & group B was 1.067 before the treatment which came down to 0.6667 after the treatment got over. The present study shows 61.53% relief in group A and 47.5 % relief in group B.

Objective parameters

The mean score of FUS in 30 patients in group A was 2.533 before the treatment which came down to 2.133 after the treatment got over & 30 patients in group B was 1.000 before the treatment which came down to 0.1333 after the treatment got over. The present study shows 86.7% relief in group A and 80.8% relief in group B.

The mean score of FBS in 30 patients in group A was 2.267 before the treatment which came down to 1.467 after the treatment got over & 30 patients in group B was 2.200 before the treatment which came down to 1.400 after the treatment got over. The present study shows 36.4% relief in group A and 30.3 % relief in group B.

The mean score of PPBS in 30 patients in group A was 2.067 before the treatment which came down to 1.267 after the treatment got over & 30 patients in group B was 2.200 before the treatment which came down to 1.467 after the treatment got over. The present study shows 38.7% relief in group A and 33 % relief in group B.

CONCLUSION

Nishamalaki found effective in Prameha. Further evaluation and research should be carried out about these drugs.

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Source of Support: Nil Conflict of Interest: None Declared