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Effect of a polyherbal formulation in management of diabetic nephropathy

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Abstract

Background: Diabetic nephropathy is the leading cause of renal failure in the United States. About 20% to 30% of the patients with diabetes develop evidence of nephropathy. Initial treatment of diabetic nephropathy, as of other complications of diabetes, is prevention. Like other micro vascular complications of diabetes, there are strong associations between glucose control and the risk of developing diabetic nephropathy. The aim of our study to evaluate efficacy and safety of polyherbal formulation tablets in diabetic nephropathy.

Methods : It was a prospective study, an open labeled, randomized, comparative, active controlled, clinical study. 60 patients suffering from diabetic nephropathy having inclusion criteria coming to Kayachikitsa department were studied. Two groups were formed, including 30 patients in each group. 60 consecutive clinically diagnosed cases of diabetic nephropathy were divided into two groups. 30 Patients in Group A were given two capsules of polyherbal formulation with standard treatment twice daily orally. 30 Patients in Group B were given only standard treatment & a placebo capsule in the dose twice a daily.

Results: The levels of Microalbuminuria in group A were given two capsules of polyherbal formulation with standard treatment twice daily orally was significantly decrease 300.3 ± 4.04 compared to group B were given only standard treatment & a placebo capsule in the dose twice a daily 356.2 ± 34.93 p value was < 0.0001 which shows significance.

Conclusion: On the basis of clinical study and the statistical tests of significance in the present study we concluded that the polyherbal formulation along with conventional treatment in comparison with conventional treatment in the management of diabetic nephropathy is more effective in the management of diabetic nephropathy.

Keywords: Diabetic Nephropathy, Microalbuminuria, Polyherbal formulation, Prameha

Introduction

Prameha can be correlated to diabetes mellitus of present era. 200 million people across the globe are affected by Diabetes Mellitus. [(1)] It is estimated that this figure will be almost double in 2030. Causes behind the alarming increase in the prevalence of Diabetes Mellitus are population growth, aging, urbanization; physical inactivity & the increased incidence of obesity [(2)]. The disease is associated with number of micro vascular complications like Retinopathy, Nephropathy, Neuropathy, & No healing ulcers [(3, 4)] These complications are not only crippling but also life threatening. [(5)] Diabetic nephropathy is the leading cause of renal failure in the United States. About 20% to 30% of the patients with diabetes develop evidence of nephropathy. Initial treatment of diabetic nephropathy, as of other complications of diabetes, is prevention. Like other micro vascular complications of diabetes, there are strong associations between glucose control and the risk of developing diabetic nephropathy. Patients should be treated to the lowest safe glucose level that can be obtained to prevent or control diabetic nephropathy. In addition to aggressive treatment of elevated blood glucose, patients with diabetic nephropathy benefit from treatment with antihypertensive drugs. Renin-angiotensin system blockade has additional benefits beyond the simple blood pressure-lowering effect in patients with diabetic nephropathy. [(6)] Diagnosis of early Diabetic nephropathy & proper treatment at this stage with the help of Ayurvedic Polyherbal Formulation was definitely help to prevent the end stage renal disease.

Present study aims was to evaluate efficacy and safety of a Polyherbal Formulation containing Sariva (Hemidesmus indicus), Manjistha (Rubia cordifolia), Punarnava (Boerhaavia diffusa), Gokshur (Tribulus terrestris), and Varun (Crataeva nurvala) along with conventional treatment in comparison with conventional treatment in the management of diabetic nephropathy with special reference to Prameha Upadrava.

Material and Methods

This study was done in Department of Kayachikitsa, Arogyashala rugnalya, Ayurved Seva Sangh's, Ayurved Mahavidyalaya, Ganeshwadi, Panchavati, Nashik. The present study was a prospective type of study. It was an open labeled, randomized, comparative, active controlled, clinical study. Study subjects were selected from patients attending OPD of Ayurved Seva Sangh, Ayurved Mahavidyalaya, Ganeshwadi, Panchavati, and Nashik. Registration of patients was from April 2011.At the time of registration, the patients with exclusion criteria were not included in the study. Polyherbal Formulation contains Sariva (Hemidesmus indicus), Manjistha (Rubia cordifolia), Punarnava (Boerhaavia diffusa), Gokshur (Tribulus terrestris), and Varun (Crataeva nurvala).

Active Ingredients of diabetic care capsules (Polyherbal formulations)

Sariva (Hemidesmus indicus)

It is a diuretic, increase urination by 2 to 4 time without affective the kidneys. So used in dysuria and pittaj prameha. [7]

Punarnava (Boerhaavia diffusa)

Oral administrative of aqueous extract of plant to alloxan induced diabetes lead to significant decrease in plasma glucose level and enhancement of plasma insulin level. [8]

Gokshur (Tribulus terrestris)

It is effective in most of urinary tract disorders, promotes the flow of urine, cools and smoothens the membranes of the urinary tract and helps to removes. Its stops bleeding, nourishes and strengthens the kidneys and reproductive organs. [9]

Manjistha (Rubia cordifolia)

It is antidiabetic, especially in manjishthameha, a type of pittaj prameha. In renal calculi, 1 gm. Manjishtha powder is given three times a day for 1 week. This removes the renal stone. If not, surgical opinion is advised. [10]

Varun (Crataeva nurvala)

It destroys urinary calculi, dysuria and pain in bladder. Its bark or decoction of the roots is used in these disorders. Its main action is on urinary calculi. In urinary calculi it is given along with apamarg, gokshur , yavakshar, punarnava [11]

Preparation of medicines

Medicines were prepared under expert supervision and purchased from Surbhi Ayurveda pharmacy, Shahapur. The quantity of the each ingredient was adjusted in such a way that the extract contained in each capsule represents around 3 Gms of the crude drugs taken together wherein all the ingredients are equally represented

Duration of the treatment

The duration of the treatment was for 6 months

60 patients suffering from diabetic nephropathy having inclusion criteria coming to Kayachikitsa department were studied. 2 groups were formed, including 30 patients in each group. 60 consecutive clinically diagnosed cases of diabetic nephropathy were divided into two groups i.e. Group A and Group B. 30 patients were assigned randomly to each group.

Patients in Group A were given two capsules of polyherbal formulation with standard treatment twice daily orally.

Patients in Group B were given only standard treatment & a placebo capsule in the dose twice a daily. At the time of registration, the baseline information was taken especially with respect to sociodemographic factors, clinical findings, sing & symptom and other investigations. Thus each & every patient was followed up in Kayachikitsa department till discharge. The data thus collected was analyzed for evaluation of the role of a polyherbal formulation in management of diabetic nephropathy with special reference to prameha upadrava.

Inclusion Criteria

- Age >21yrs. & < 70 years, of both sex.
- Confirmed diagnosis of diabetes mellitus type II with DN.
- Plasma glucose is under control (fasting plasma glucose<140 mg/dl, PPBSL <200, glycosylated haemoglobin<7.0%) with oral glucose-lowering agents and /or insulin;
- Raised micro-albuminuria suggesting early diabetic nephropathy with serum creatinine. (1.5-4 mg/dl)
- Rise in eGFR 24 hrs. Urine creatine, Sr. creatinine, Blood urea. BUN. Sr. uric acid

- Microalbuminuria or Overt proteinuria is present
- (urine albumin > 300mg/d in a 24-h collection)
- Given consent for participation

Exclusion Criteria

- No diabetic nephropathy
- Diabetic ketoacidosis within the last 6 months;
- Significant reduction/elevation in abnormal Calcium, Phosphorus & electrolyte levels requiring immediate management.
- Any other serious systemic disease within the last 3 months;
- With obvious symptoms or signs of liver diseases, ALT or AST > two times normal upper limit;
- Severe oedema or serous cavity effusion;
- Drug abuse
- Suffering from any malignancy.
- Receiving the long-term systematic steroid, hormone treatment;
- Gestation already, prepares to be pregnant in the period of the trial, lactating women;
- Participate in other product clinical trial within 30 days prior to this trial.
- History of previous kidney transplant
- Patients unwilling to give consent.

Laboratory investigations carried out were

After overnight fast (10-12 hrs.) blood sample for blood glucose were collected in fluoride vial and blood urea, Blood urea nitrogen in chemistry bulb. For Serum creatinine, uric acid, uric acid, were collected in plain vial between 8am to 10 am. Sample was centrifuged at 3000 rpm for 10 minutes; serum were separated and immediately stored in deep freezer at – 20^{o}C until further analysis. Fresh urine sample were collected for albuminuria. Biochemical investigations FBG by GOD and POD, [12] serum Uric Acid by Caraway's method. [13] Creatinine by Jaffe's Method, urine Creatinine by Jaffe's Method, [14] Blood Urea by DAM method [15], BUN by calculation , estimated Glomerular filtration rate (eGFR) by calculation and microalbumineuria were performed by Micral-test Microalbuminuria®, Roche Diagnostics GmBh.

Statistical Analysis

SPSS (Chicago, IL, USA) version 21 was used for statistical analysis of data. Descriptive statistics for quantitative variables were presented as mean ± SD. Analysis of variance (ANOVA) was used to compare between group A and Group B, $P<0.05$. Sing and Symptoms grades of diabetic nephropathy were analysis by chi square test, $P<0.05$.

Results

Table 1: Comparison of biomarkers in group A compared to group B

Variable	Group A	Group B	P Value
Sex M/F	18/12	18/12	--
Age	47.56 ± 9.37	47.56 ± 9.37	1
Fasting Blood Glucose level (mg/dl)	115.12 ± 5.93	161.70 ± 21.77	<0.0001
Serum uric acid (mg/dl)	5.7 ± 0.34	6.6 ± 0.45	<0.0001
serum Creatinine (mg/dl)	1.33 ± 0.18	1.79 ± 0.28	<0.0001
U. Creatinine (gm/day)	1.14 ± 0.08	2.33 ± 0.47	<0.0001
Blood Urea (mg/dl)	39.71 ± 3.0	49.6 ± 4.88	<0.0001

BUN (mg/dl)	18.47 ± 2.66	26.9 ± 3.52	<0.0001
eGFR (ml/minute)	119.31 ± 2.16	111.7 ± 4.6	<0.0001
Microalbuminurea (mg/day)	300.3 ± 4.04	356.2 ± 34.93	<0.0001

Applying t test. p <0.05, was shows statistical significance

Graph 1: Micro Albuminurea mg/ day.

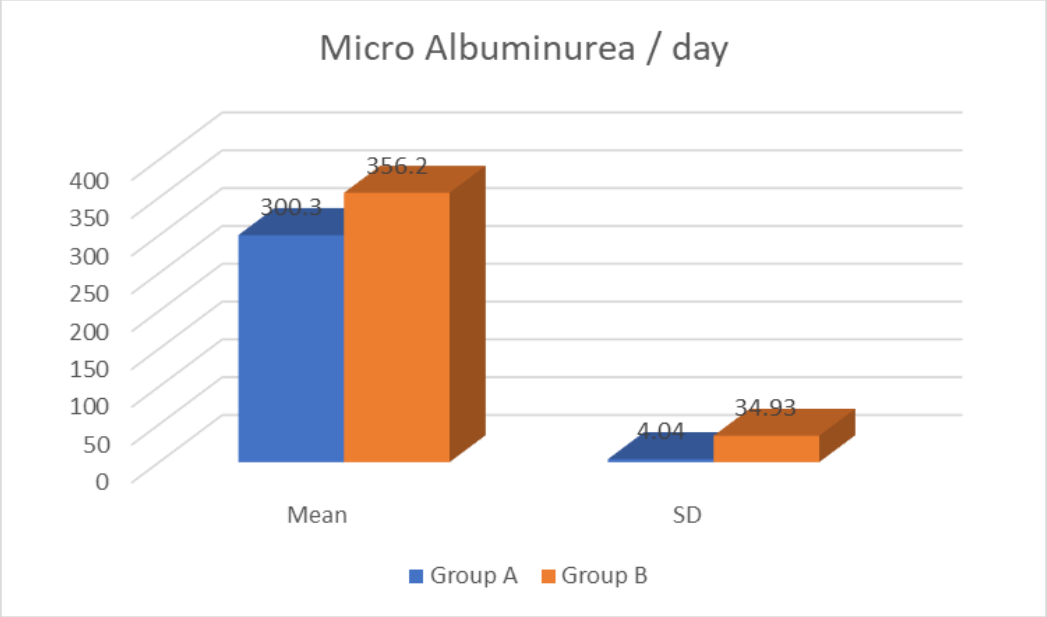

Table 2: Effect on Sing and Symptom of diabetic nephropathy

Sing and Symptom	Groups	Grade 0	Grade 1	Grade 2	Grade 3	Total	P value
Mukhshotha	A	6 (20%)	24 (80%)	0 (0%)	0 (0%)	30 (100%)	<0.0001
	B	0 (0%)	2 (6.66%)	15 (50%)	13 (34.34%)	30 (100%)	
Padashotha	A	10(33.33%)	18 (60%)	2 (6.67%)	0 (0%)	30 (100%)	<0.0001
	B	2 (6.67%)	5 (16.66%)	14 (46.67%)	9 (30%)	30 (100%)	
Shwaskashthata	A	6 (20%)	21 (70%)	3 (10 %)	0 (0%)	30 (100%)	<0.0001
	B	1 (3.33%)	3 (10%)	15 (50%)	11 (36.67%)	30 (100%)	
Panduta	A	9 (39%)	20 (66%)	1(3.34%)	0 (0%)	30 (100%)	<0.0001
	B	0 (0%)	1 (3.34%)	14(46.66%)	15 (50%)	30 (100%)	
Dourbalya	A	10 33.34%)	18 (60%)	2 (6.66%)	0 (0%)	30 (100%)	<0.0001
	B	0 (0%)	2 (6.66%)	21 (70%)	7 (23.34%)	30 (100%)	
Twakrukshata	A	6 (20%)	24 (80%)	0 (0%)	0 (0%)	30 (100%)	<0.0001
	B	0 (0%)	2 (6.66%)	21 (70%)	7 (23.34%)	30 (100%)	

Applying chi square test. p <0.05, was shows statistical significance

The levels of microalbuminuria in group A was 300.3 ± 4.04 compared to group B 356.2 ± 34.93 p value was < 0.0001 which shows significance. (Table. No.1 & Graph.No.1). Mean score of Fasting blood glucose in group A was 115.12 ± 5.93 compared to group B 161.70 ± 21.77. p value was < 0.0001 which shows significance. Mean score of serum uric acid in group A was 5.7 ± 0.34 compared to group B 1.79 ± 0.28. p value was < 0.0001 which shows significance. Mean score of serum Creatinine in group A was 1.33 ± 0.18 compared to group B 1.79 ± 0.28. p value was < 0.0001 which shows significance. Mean score of urine Creatinine in group A was 1.14 ± 0.08 compared to group B 2.33 ± 0.47. p value was < 0.0001 which shows significance. Mean score of blood urea in group A was 39.71 ± 3.0 compared to group B 49.6 ± 4.88. p value was < 0.0001 which shows significance. Mean score of blood urea nitrogen (BUN) in group A was 18.47 ± 2.66 compared to group B 26.9 ± 3.52. p value was < 0.0001 which shows significance. Mean score of eGFR in group A was 119.31 ± 2.16 compared to group B 111.7 ± 4.6. p value was < 0.0001 which shows significance. (Table no.1)

Discussion

In the diabetic patients, nephropathy develops mainly due to glomerular sclerosis and arteriosclerosis in kidneys. Kidney tissues get damaged after some period. According to Ayurveda, nephropathy is a disease of Mutravaha Srotas. Though all the three doshas are involved in the disease, Kapha is responsible in blocking microvessels and developing microangiopathy. Damage in tissue can be repaired and prevented by the use of Rasayanas as they improve the nourishment, maintain the patency of the Srotas and improve the resistance of the tissues against any adversity. Any blockage can be removed by the preparations having Lekhana (scraping) effect on blocked microvessels as well as macrovessels.

Gokshura, the main ingredient, is well known for its Rasayana effect, especially on Mutravaha Srotas. Punarnava (Boerhavia diffusa) is an excellent medicine in this condition due to its tridoshar, kaphapittashamak, shothhar, mutrajanan properties [16]. Varun (Crataeva nurvala) also pacifies kapha and vata and especially reduces pain in basti. It is well known as mutramargsankramana. [17], Gokshura , Varun, Sariva, Manjishtha, Punarnava formulation also works on Mutravaha Srotas. Hence, this polyherbal formulation has been selected for the treatment of diabetic nephropathy.

A prospective study was conducted among 60 cases to evaluate the role of polyherbal formulation in management of Diabetic Nephropathy with special reference to Prameha Upadrava.

Though some herbal medicines have been tested for their efficacy in DN, many mono herbal or poly herbal medicines remain largely unexplored. Especially, medicines used in indigenous and classical texts and are known to have beneficial effects in renal diseases are worth exploring. Hence in the present study, herbal medicine such as Gokshura (T. terrestirs Linn.) which is easily available, widely practised in treatment of diseases related to urinary system (mutravaha srotasa) and DM (prameha) was selected. For use of standardized drug, maintaining the standard dose and easy palatability, it was decided to use the medicine in capsule form. All ayurvedic principles were kept in mind while preparing the extract of the study medicine.

In present study, among both groups majority 70% patients were in age group of 41 to 60 years. Average

Age in years of group A and of group B years. Was shows no statistical significance. Similarly Study by Deshpande V et al [18] showed that mean age of group A was 61.4±6.15 and group B was 58.25±7.97 years. P value was not significant. In present study, among both groups majority 60% patients were males as compared to females. Was shows no statistical significance. Study by Deshpande V et al [18] showed that majority were males among both groups. was not significant.

In present study, among group A majority 80% had grade 1 mukhshotha and among group B 50% had grade 2 and 43.34% had grade 3. was shows statistical significance. Study by Deshpande V et al [18] showed that P value (0.03) was significant. In present study, among group A majority 60% had grade 1 and 33.33% had grade 0 Padashotha and among group B 46.6% had grade 2 and 30% had grade 3. Study by Deshpande V et al [18] showed that P value (0.42) was not significant. In present study, among group A majority 70% had grade 1 and 20% had grade 0 Shwasa kashthata and among group B 50% had grade 2 and 36.67% had grade 3., was shows statistical significance. Study by Deshpande V et al [18] showed that P value (0.03) was significant. In present study, among group A majority 66.66% had grade 1 and 30% had grade 0 Panduta and among group B 46.66% had grade 2 and 50% had grade 3. Was shows statistical significance. Study by Deshpande V et al [18] showed that P value (0.58) was not significant. In present study, among group A majority 60% had grade 1 and 33.34% had grade 0 Daurbalya and among group B 70% had grade 2 and 23.34% had grade 3. Was shows statistical significance. Study by Deshpande V et al [18] showed that P value (0.04) was significant. In present study, among group A majority 80% had grade 1 and 20% had grade 0 Twakrukshata and among group B 70% had grade 2 and 23.34% had grade 3. Was shows statistical significance. In subjective analysis, symptoms namely facial oedema (mukha shotha), pedal oedema (pada shotha), dysponea (shwasa kashtata), pallor (panduta), weakness (daurbalya), and Twakrukshata showed significant improvement in group B as compared to group A. It shows usefulness of the drug under study in relieving of symptoms of Nephropathy.

In present study, serum Creatinine, serum uric acid among group A mean S. uric acid was 5.7±0.34 and for group B was 6.6 ± 0.45. Applying t test, p value<0.0001, shows statistical significance. In present study, among group A mean S. creatinine was 1.33±0.18 and for group B was 1.79 ± 0.28. Applying t test, p value<0.0001, shows statistical significance. Study by Deshpande V et al [18] showed that mean S creatinine for group A was 1.22±0.34 and group B was 1.17±0.28. P value was not significant.

In present study, among group A mean urea was 39.71±3 and for group B was 49.6 ± 4.88. Applying t test, p value<0.0001, was shows statistical significance. Study by Deshpande V et al [18] showed that mean urea of group A was 29.82±10.9 and group B was 31.23±10.31. P value was not significant. Another study by Patel K et al [19] In present study, among group A mean BUN was 18.47±2.26 and for group B was 26.9 ± 3.52. Applying t test, p value<0.0001, as p <0.05, shows statistical significance. Study by Deshpande V et al [18] showed that mean BUN of group A was 13.85±5.23 and group B was 11.64±2.33. P value was not significant. In present study, among group A mean eGFR was 119.31±2.16 and for group B was 111.7 ± 4.6. Applying t test, p value<0.0001, shows statistical significance. In present study, among

group A mean U. Creatinine/day was 1.14±0.08 and for group B was 2.33 ± 0.47. Applying t test, p value<0.0001, shows statistical significance.

In present study, among group A mean Micro Albuminurea / day was 300.3±4.04 and for group B was 356.2 ± 34.93. Applying t test, p value<0.0001, as p <0.05, shows statistical significance.

Study by Deshpande V et al [18] showed that mean protein for group A was 585.15 and in group B was 383.9. P value was not significant. Study by Modak M et al [16] showed that punarnava increase in hexokinase activity, decrease in glucose-6-phosphatase and fructose bis-phosphatase activity, increase plasma insulin level, antioxidant. It acts as chief drug in maintaining the diabetic complications i.e diabetic nephropathy. Another study by Pari L et al [17] conducted a study with the purpose of this study was to investigate the effects of daily oral administration of aqueous solution of Boerhaavia diffusa L. leaf extract (BLEt) (200 mg/kg) for 4 weeks on blood glucose concentration and hepatic enzymes in normal and alloxan induced diabetic rats. A significant decrease in blood glucose and significant increase in plasma insulin levels were observed in normal and diabetic rats treated with BLEt. Treatment with BLEt resulted in a significant reduction of glycosylated haemoglobin and an increase in total haemoglobin level. The activities of the hepatic enzymes such as hexokinase was significantly increased and glucose-6-phosphatase, fructose-1,6-bisphosphatase were significantly decreased by the administration of BLEt in normal and diabetic rats. An oral glucose tolerance test (OGTT) was also performed in the same groups, in which there was a significant improvement in glucose tolerance in rats treated with BLEt. A comparison was made between the action of BLEt and antidiabetic drug-glibenclamide (600 microg/kg). The effect of BLEt was more prominent when compared to glibenclamide.

There was no evidence of any adverse effect of the polyherbal formulation in this study.

Conclusion

On the basis of clinical study and the statistical tests of significance in the present study we were concluded that the polyherbal formulation containing Sariva (Hemidesmus indicus), Manjistha (Rubia cordifolia), Punarnava (Boerhaavia diffusa), Gokshur (Tribulus terrestris), and Varun (Crataeva nurvala) along with conventional treatment in comparison with conventional treatment in the management of diabetic nephropathy is more effective in the management of diabetic nephropathy with special reference to Prameha updrava.

Registration: The study is registered in Clinical Trial Registry of India vide number CTRI/2015/10/009913 (date: 09/10/2015).

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