

EVALUATION OF EFFECT OF *PUNARNAVA GHANVATI* IN *PRAMEHA UPDARVA* WITH SPECIAL REFERANCE TO DIABETIC NEPHROPATHY

BhavanaS.Mane¹, Sandeep Gorakh Mane²

¹Associate professor Swasthavritta Department

²M.D.Kayachikitsa, Associate professor Kayachikitsa department
Siddhakala Ayurved College, Sangamner, Ahmednagar, Maharashtra, India

Email: drsgmane@gmail.com

ABSTRACT

Diabetis mellitus is silent killer, 2nd ranked disease leading to cause death. India has already becomes the diabetes capital of the world, over 3 crores affected patient. By 2025 it is estimated that approximately 80 million Indians will be diabetic and more than 200 million will be diabetics within next 10 year. Acute complications are metabolic and infection where as chronic complication are macroangiopathy and microangiopathy. Diabetic are at increased risk for several types of kidney disease but the predominant cause of end stage renal disease in diabetics is diabetic nephropathy, account for second most important cause of Renal disease consisting about 18.56%. *Prameha vyadhi* described in our samhita Grantha is having similarity with modern Diabetes mellitus. In the disease progress, continuous loss of *Dhatu* through urine due to *dhatushaithilya*, *humpers* the strength of *Dhatu* resulting into deterioration of *Dhatushaithilya*. Therefore, need was felt to study on this topic with possible best remedy in order to find better solution for management of Diabetic nephropathy, to improve quality of life. We should have such kind of drug which can remove the *avarodha* formed by *meda & kleda*. Prevent *Dhatuksharan* through *mootravaha srotas*. For the purpose of convenience of administration and to maintain standard it was decided to give this particular drug in the form of Ghanavati. The present study aims, Evaluation of affect of *Punarnava Ghanavati* in *prameha upadrava* with special reference to Diabetic Nephropathy.

Key words: *Punarnava, prameha, ghanvati, chikitsa*

INTRODUCTION

‘*Swasthya Swasthya Rakshanam Aturasya Vyadhipari Mokshaha*’ this is the basic principle of Ayurveda. Along with maintenance of healthy status, various diseases, their prin-

ciples of etiology, Pathophysiology, Symptomatology and treatment measure are also mentioned in great details in Ayurveda and diabetes mellitus is not an exception. Detail description

of diabetes mellitus is given in various *samhita granthas* under the name *prameha* which mean *Prabhuta Mutrata* (excessive Urination) and *Avil Mootrata* (Turbid Urination).

Diabetic nephropathy is mainly characterized by the gross proteinuria (3.5m/24hrs), developing after 10 yrs duration of diabetes mellitus.

As per modern science management of Diabetic nephropathy consist of, tight glycemic control, control blood pressure by ACE inhibitors and ARB, Dietary protein restriction. In spite of this, they may control the progression of the disease but solution for cure is still awaited. Those drugs which are used, has got so many side effect. Once the patient with Diabetic nephropathy progress to stage 5 (ESRD), dialysis, and renal transplantation is implemented. Recurrent dialysis & renal transplantation is highly cost effective for patient. But overall result is frustrating. Therefore, need was felt to study on this topic with possible best remedy. In order to find better solution for management of Diabetic nephropathy, to improve quality of life

MATERIALS AND METHODS

The study entitled “Evaluation of the effect of *Punarnava Ghanavati* in *Prameha Upadrava* with special reference to Diabetic Nephropathy” primarily aims at the clinical evaluation of the effect of *Punarnava Ghanavati* in Diabetic Nephropathy. The present study had also undertaken the review of Ayurvedic literature in order to find out missing links in Nephropathy mentioned in Ayurveda. Along with Ayurvedic literature Modern literature was also searched for the understanding of Diabetic Nephropathy.

Design of study: Open controlled study.

Place of study: Department of Kayachikitsa, M.A. Podar Hospital

Subject recruitment and screening

Diabetic patients presenting with the symptoms of Diabetic Nephropathy were selected from OPD & IPD of the M.A. Podar Hospital. Primary detailed systemic examination was carried out in each subject for the observation of illness including evaluation of renal deficits. On the basis of laboratory evidence and subjective examination the patients were included in project. Before including each subject was informed regarding the disease and its available management as well as the medicine (*Punarnava Ghanavati*).

Consent – A written consent of all patients included in the trial, in the language best understood to them, was taken before entering them in the trial.

INCLUSION CRITERIA FOR STUDY SUBJECTS

1. Patients of either sex were included in study.
2. Patients in the age group of 35 to 75 yrs. were included.
3. Subjects without any psychological disturbances were included in order to avoid its influence on the conduct of the study or interpretation of results.
4. K/C/O – Diabetes mellitus having laboratory evidence and presenting with the symptoms of Diabetic nephropathy were selected for the trial.
5. Subjects having serum creatinine value less than 4mg.
6. Subjects having Blood Urea level less than 80 mg/dl were included.

EXCLUSION CRITERIA FOR STUDY SUBJECTS –

1. Patients having age below 35 yr and above 75 yrs were excluded.
2. Subjects with any psychological disturbances were excluded in order to avoid its influence on the conduct of the study or interpretation of results.
3. Subject having Sr. Creatinine value more than 4 mg/dl were excluded.
4. Subjects having Blood Urea level greater than 80 mg/dl were excluded.
5. Patients with severe acute complication of Diabetes mellitus were not included in study.

GROUPING OF PATIENTS:

Group 1:

20 Diabetic patients with good glycemic with O.H.A. and or insulin and presenting symptoms of Diabetic nephropathy were given the drug *Punarnava Ghanavati* in recommended dose. For assessment of Glycemic control glycated hemoglobin test was done. For objective analysis of Diabetic nephropathy, 24 hr Urine protein and creatinine clearance investigations were advised. All the routine investigations were carried out at the intervals / stage as mentioned.

Group 2:

20 Diabetic patients with good glycemic control with OHA and or insulin and presenting symptoms of Diabetic Nephropathy were given the conventional treatment of Diabetic nephropathy. For assessment of Glycemic control glycated hemoglobin test was done. For objective analysis of Diabetic nephropathy, 24 hr. Urine protein and creatinine clearance investigations are advised. All the routine investigations were carried out at the intervals/stage as mentioned.

DRUG USED PUNARVANA GHANAVATI

Punarnava Ghanavati is Ayurvedic formulation the *Ghanavati* to crude drug ratio was 1: 09 i.e. 1 gm of *Ghnavati* was extracted from 09 gms of crude drug. The drug is made in the form of *Ghanavati* for the ease and palatability. Chaitanya Pharmacy, Nasik prepared the drug for the trial. This help is duly acknowledged. All Ayurvedic principles were kept in mind while preparing the drug. The strength of each *Punarnava Ghanavati* is 250 mg. Dose – 1 gm 4 times a day. *Anupan – Koshan Jala*.

Diet – Special diet as prescribed for diabetic Nephropathy shall be advised to patients in both the groups.

Duration of Treatment: Twelve Weeks (3month).

OBSERVATIONS DURING THE COURSE OF THE STUDY

Patients with persistent protein via for 3 successive realings were advised the investigations such as 24 hr urine protein, creatinine clearance, glycated hemoglobin.

Parameters of assessment:

Assessment of patients was done subjectively as well as objectively.

Subjective assessment:

Symptoms of Prameha Upadrava with special reference to Diabetic Nephropathy mentioned in the texts or practically observed were assessed at each follow up. Presence or absence of these symptoms was registered. Different symptoms were graded into four grade scale (0 to 3) on the basis of severity to assess the changes in clinical symptoms of Diabetic nephropathy.

Objective assessment:

For the objective assessment of Diabetic nephropathy, 24 hr Urine protein, creatinine clearance was done at the starting and end point

of the study. Efforts were made to maintain tight blood sugar control through the period of trial. Glycated hemoglobin (HbA1C) was estimated at the entry point and at the end of the study to assess the level of average glycemic control.

Statistical Analysis-

For Final result & conclusion study data was subjected to statistical analysis. 'Student T-test' is applied to find out the significance of the improvement. Pretreatment and post treatment reports of 24 hr. Urine protein, creatinine clearance were compared to see the improvement.

STATISTICAL ANALYSIS-

Assessment of Objective Variables :-

1. 24 HOUR URINE PROTEIN-

In trial group, initial reading of 24 hour Urine protein was 337.15 ± 345.55 mg while at the end of study (after 12wk) the reading was 333.55 ± 341.37 mg/24hrs.

Initially in controlled group the 24 hour urine protein were 275.75 ± 150.78 mg/24hrs and at the end of study the mean protein excretion through urine was estimated as 246.35 ± 139.61 mg/24hrs. which is statistically significant ($P < 0.05$).

2. CREATININE CLEARANCE.

At the baseline, in trial group the mean creatinine clearance was 50.68 ± 9.74 and at the end of the study that was 65.08 ± 11.84 which is significant

In another group mean creatinine clearance was 53.39 ± 17.45 and lastly that was 53.65 ± 19.11 which is not significant ($P > 0.05$) (Table No. Group No. 15, Graph No.14).

3. Glycated HEmoglobin (HbA1C)

As the Glycemic control plays a very vital role in Diabetic nephropathy it was decided to include the patients having good glycemic

control. This investigation was done before and after the treatment to assess the status of Diabetes during the trial.

Initial mean Glycated hemoglobin value in trial group was 7.65 ± 1.07 and final value was 7.87 ± 1.04 and in case of controlled group mean Glycated hemoglobin was 7.46 ± 0.40 and final value was 7.61 ± 0.46 . Statistically no significant variation is noted which suggests good glycemic control of patient. (Table No.17)

4. Blood Sugar Fasting.

Initial mean blood sugar fasting value in trial group was 140.25 ± 38.17 mg/dl and final value was 138.9 ± 36.60 mg/dl.

Initial mean Blood sugar fasting value in controlled group was 148.25 ± 46.85 and final value was 142.15 ± 44.80 mg/dl. From above observation it is clear that there is no statistical significance in fasting blood sugar level.

Blood Sugar Post-Prandial

Initial mean sugar postprandial value in trial group was 243.4 ± 57.21 mg/dl final value was, 236.5 ± 66.52 mg/dl

Initial mean blood sugar post prandial value in controlled group was 237 ± 38.60 and final value was 245 ± 50.12 there is no significant change in post prandial blood mg/dl sugar level in both group. (Table No.17)

8) Initially mean of sr cholesterol was 190.75 ± 36.22 and finally was 180.75 . In controlled group mean was 209.45 ± 43.23 initially and 216.25 ± 43.88 finally compare to both groups it can be say that Punarnava Ghanavati does act on serum cholesterol level by reducing it.

9) Initially Sr Triglyceride level in trial group was 152.25 ± 5.69 and after studies it was 137.95 ± 36.87 and in case of controlled group initial value was 168.1 ± 39.96 and final value was 149.95 ± 46.15 .

Assessment of Subjective Variables

Symptoms of Diabetic nephropathy given in text and practically observed were assessed at regular interval of each follow up. Presence or absence of these symptoms was registered. Different symptoms were graded into four grade scale as per severity to assess the changes in clinical symptoms of Diabetic Nephropathy.

- **Group 1:** The mean grade scores of mukhashotha in patients of this group at the beginning of the study was 1.15 ± 0.67 it came down to 0.2 ± 0.41 at the end of study 14 patients were in grade '0' at the end of the study.
- **Group 2:** At the starting the mean grade score of mukhashotha in patients of controlled group was 1.9 ± 0.7 and it comes to 1.7 ± 0.5 at the end of the study.
- **Group 1:** The mean grade scores of padashotha was 1.7 ± 0.65 to begin with and at the end of the study that was 0.35 ± 0.67
- **Group 2:** Mean Pathodoshatha in this group was 1.55 ± 0.94 initially and 1.15 ± 0.81 finally. There was gradual reduction in pathodoshatha symptoms seen in trial group patient
- **Group 1:** The mean grade score of these symptoms initially was 1.65 ± 0.48 and that of end of the study was 0.5 ± 0.6 . There were 11 patients in the study who were totally free from these symptoms.
- **Group 2:** The mean grade score of Shwaskashtata in this group was 1.5 ± 0.6 and at the end of study that comes to 1.25 ± 0.7 .
- **Group 1:** Initially score was 1.85 ± 0.58 and finally score was 1.85 ± 0.4 .

- **Group 2:** The mean grade score of panduta in this group of patient was 2.05 ± 0.39 and by the end of study that was 2.15 ± 0.36 . Above observation shows that there was no any statistical significance in case of panduta, but in trial group patient's Haemodynamic Status same and in controlled group it worsened further.
- **Group 1:** The mean grade score in Daurbalya in trial group was 1.7 ± 0.4 initially and 0.8 ± 0.61 finally. This shows the significant improvement in this symptom.
- **Group 2:** The mean grade score in this group of patient for Daurbalya was 0.85 ± 0.48 initially and 1.3 ± 0.57 finally.
- **Group 1:** Mean grade score of Aruchi, initially was 1 ± 0.72 and 0.5 ± 0.51 finally.
- **Group 2:** Mean grade score of this symptoms in this group of patient was 0.85 ± 0.48 and 0.85 ± 0.48 initially and finally respectively. Trial group shows significant improvement.
- **Group 1:** The mean grade score initially was 1.85 ± 0.74 and 1.1 ± 0.9 finally.
- **Group 2:** The mean grade score of mutral-pata in this group of patient was 1.9 ± 0.64 which comes to 1.7 ± 0.6 finally.
- **Group 1:** In case of Agnimandya the mean grade score was 1.35 ± 0.183 initially and it was 0.7 ± 0.83 at the end of the study It shows significant improvement in this group of patient.
- **Group 2:** The initial score of Agnimandya was 1.25 ± 0.78 which increases to 1.35 ± 0.8 at the end of the study. (Table No.21, Graph

DISCUSSION

In present study statistical analysis showed that, *Punarnava Ghanavati* is quite effective in eliminating the wastage end product of metabolism like creatinine, Blood urea. Increase of these metabolic endproduct in body results into symptoms like *Aruchi*, *Agnimandya*, fatigue, debility, dyspnoea on exertion etc. it is marker of unsatisfactory renal function.

In trial group increased protein loss was observed in 2 patients, in 13 patients it was constant and 5 patient were improved. In controlled group protein loss was increased in any patients 6 patients were having stable protein loss and patients shows significant decrease in protein loss. As the above observation shows better result with second group but it can be seen that Although *Punarnava Ghanavati* not able to decrease the protein loss but it stabilizes it, maintaining renal function in continuous protein phase.

Mean creatinine clearance shows significant increase after trial study. 13 patients improved, 6 remain in constant state and only one patient deteriorate. In controlled group 3 patient were improved, 14 remains in constant state and 3 patients shows decreased creatinine clearance. Creatinine clearance is marker of capacity of kidney to filter urine. Decline in creatinine clearance shows decreasing filtration capacity of kidneys. Increase in the value of creatinine clearance is certainly suggestive of increased capacity of kidney. In our study there is a significant rise in creatinine clearance level in majority of patient. It shows that *Punarnava Ghanavati* is effective in draining out creatinine from body and ultimately increasing renal capacity to excrete it.

In subjective analysis in symptoms such as *mukhashotha*, *Daurbalya*, *Agnimandya*, *Aruchi*, significant improvement is experienced as

compared to controlled group. It shows efficacy of the drug under study in relieving of symptoms of nephropathy. In trial group and in controlled group there is no significant variation regarding the glycemic control is noted in controlled group there is no. The mean blood sugar fasting and post prandial values remained almost stable.

CONCLUSION

The present study entitled. Evaluation of effect of *Punarnava Ghanavati* in *Prameha Upadrava* with special reference to Diabetic nephropathy has the aim of evaluating the clinical efficacy of *Punarnava Ghanavati* in Diabetic Nephropathy. An effort was made to review the detailed literature available on *prameha* in all *Samhita Granthas* along with commentaries. *Vrikka Roga* described in Ayurveda was also taken into consideration to clear the Ayurvedic concept of Nephropathy.

A total of 40 patients suffering from Diabetic nephropathy were included in the study. Symptomatic improvement was found in almost all the patients of Diabetic nephropathy treated with *Punarnava Ghanavati* while those who were on conventional treatment most of the symptoms remain unchanged. Moreover the study was conducted to find the efficacy of *Punarnava Ghanavati* in Diabetic Nephropathy but to manage the disease, combination of therapies can be administered. No untoward effect was observed during the total study period.

The possible mechanism of action of *Punarnava Ghanavati* is virtue of its *Mutral*, *mutravaha srtogamitwa*, *shothghna*, and *rasayam* properties. It has *Tridosha shamak* property, Due to this Acharya have recognized it as a remedy in *Tridosha Janya Vyadhi-prameha*. It is *Tikta*, *Kashaya*, *Katu* in Rasa hence able to

break the *srotorodha* formed by *meda*, *kleda* and *kapha*. *Tikta Rasa* improves appetite, digestion. *Punarnava* has *laghu Guna* which is necessary to stimulate *Jathragni*. *Sheeta virya* of *Punarnava* may gives stability to the *dhatu* more over it possesses *Rasayan* property thus replenishes the lost *Dhatu*s by absorption of excessive liquefied *dhatu* and draining it into *mutravahi strotas* from where it excrete as urine, produces the *Dhatu*s having appropriate strength and qualities and improves the *Vyadhikshamatwa* (Body tissue resistance against disease mechanism).

From over all S trial study it can be say that *Punarnava Ghanavati* may become a good remedy in Diabetic nephropathy. But detailed studies with Histopathology are necessary in vitro and vivo, to evaluate the efficacy of *Punarnava Ghanavati* in reversing the early changes of Diabetic Nephropathy, arresting the progression of pathogenesis of the disease, correction of structural as well as functional deformity of renal tissue get affected in the disease

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