

**RANDOMISED COMPARATIVE CLINICAL STUDY TO EVALUATE
THE EFFECT OF TRAYUSHNADI GUTIKA WITH AND WITHOUT
VIRECHAN BY ABHYADI MODAK IN PRAMEHAJANYA UPDRAV
WITH SPECIAL REFERENCE TO DIABETIC NEPHROPATHY**

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Article Received on
01 June 2022,

Revised on 21 June 2022,
Accepted on 11 July 2022

DOI: 10.20959/wjpr202210-24938

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ABSTRACT

As the cases of Diabetes mellitus (DM) are increasing, its complications are becoming more and more prevalent. The Diabetes currently affects about 8.8% of the Indian population.^[1] Hence there is need to prevent patients from becoming dependent on external insulin dosages and lifelong intake of oral medications, which may further make the prognosis worse. Though management of Diabetic Complication is possible by Modern medicines, it has its own fallacies. Both Shodhan and shaman chikitsa have been mentioned in the Ayurvedic texts for the treatment of Prameha using various formulations which have significant results. Here two groups were taken for the study of Trayushnadi gutika with or without virechan, each group having 25 patients. Virechan was done using Abhyadi

Modak. The Objective and subjective parameters both were taken for analysis and statistics were applied. The effect seen during the time period of 3 months (90 Days) in both the groups will be discussed in this article.

KEYWORDS: Diabetic Complications, Prameha Updravas, Diabetes, Ayurveda, Diabetes Mellitus, Chikitsa.

INTRODUCTION

Diabetic Nephropathy has significant presence, with the increasing Diabetes cases, in today's era. Studies conducted in Asian countries reported variability in the prevalence rate of Microalbuminuria which is the diagnostic criteria for identifying Diabetic Nephropathy, ranges from 14.2% in Iran, 24.2% in Pakistan, to 36.3% in India in Diabetes Type 2 patients.^[2] Currently, diabetic nephropathy is the leading cause of chronic kidney disease in the United States and other Western societies and Asia. Hence there is need to prevent the patients from becoming dependent on dialysis which may further make the prognosis worse. Though management of Diabetic Nephropathy is possible by Modern Medicines, it has its own fallacies. In surgical management, costly procedures like renal transplantation are done. Dialysis again has its own fallacies. Meanwhile how much Ayurvedic treatment can provide relief is yet to be explored fully.

Review of literature

A) Modern review

Depending upon etiology of DM, hyperglycemia may result from the Following^[3]:

- Reduced insulin secretion
- Decreased glucose use by the body
- Increased glucose production.

B) There are three phases of development

1. *phase* has Euglycemia with increased insulin levels
2. *Phase* has post prandial hyperglycemia with increased insulin secretion.
3. *Phase* shows overt diabetes with declining insulin levels.

Pathophysiology of diabetic nephropathy involves an interaction of metabolic and haemodynamic factors. The central features of Pathogenesis of Diabetic Nephropathy are,

- 1) Activation of renin -angiotensin system-leading to both intrarenal and systemic effect.
- 2) Direct effect of prolonged hyperglycemia-leading to renal inflammation and fibrosis.^[4]

Ayurvedic review

Updrava/Complications of disease

Updrava is one which occurs in the course of some other disease, although it may result from the main disease.

The origin of upadrava is either due to improper management of disease or the continuation of vyadhi nidanas.

Sushruta mentions word Aupasargika as a synonym to Upadrava.^[5]

It also means that Upadrava manifests upon another disease and also due to same factors which are responsible for the manifestation of the main disease.^[6]

Hence management of upadrava is having at most importance or significance in Ayurveda.

The sneha preparations of Sarshapa, Nikumbha, Karanja, Trikantak are to be used for this purpose.

The description of Kaphaja, Pittaja and Vataja Upadravas is not limited only to the respective Pramehas. Therefore the Kaphaja, Pittaja and Vataja Upadravas are the result of the disease according to the predominance of the respective Doshas in the severe form of Prameha.^[7]

Probable samprapti of diabetic nephropathy

As per the description of complications of disease specially Diabetes here described in ayurvedic and modern perspective both, the probable samprapti of Diabetic Nephropathy from ayurvedic perspective can be described as below.

A. Dosha Dushti

1. Kapha - Kledaka Pradhan (Drava, Guru, Pichhila)
2. Pitta - Pachak Pradhan
3. Vata - Apana Pradhan Vyana vayu

B. Dhatu Dushti– All dhatus (Except Asthi) Vasa Lasika, Ojus, Ambu

C. Agni Dushti – Meda Dhatvagni Mandya

D. Adhithana - Vrikka

E. Strotasa - Medovaha, Mutravaha, Udakvaha

F. Strotas Dushti Prakara - Sang / Vimarggman

G. Vyadhi Utpatti Sthanam – Medadhatu, Vrikka

H. Vyadhi Sanchar Sthanam -MutravahaStrotas

- RasahaStrotas
- Raktavaha Strotas
- Pranvaha Strotas

I. Vyadhi Adhithana - Vrikka

J. Vyadhi Vyaktisthana - Mutravaha Strotasa,

- Rasavaha Strotasa,
- Raktavaha Strotasa,
- Pranavaha Strotasa
- K. Prakop Swabhava – Chirkalin Prakopa
- L. Vyadhi Swabhava -Chirkari
- M. Vyadhi Marga – Aabhyantar
- N. Vyadhi Vaisheeshtya – Muthralpata, Shotha (Specially of disease or pratyatma linga)
- O. Dhatugata Avastha – Sarv Dhatugata Avastha
- P. Sadhyaasadhya – Krichha Sadhya
- Q. Chikitsa Parinam – Chirkari (Cronic Proper Management is required and the results show encouraging effect on morbidity and moratality of patient)
- R. Rugna Vaya Sambandha - Vardhakyavastha>Yuvavastha (Relation of age factor) (old age > Young age)
- S. Sex → Female = Male
- T. Sankramana – Non infectious
- U. Anuvansheekatva – Anuvanshik Vyadhi (Hereditary factor) (Hereditary Disease)
- V. Dhatugata Prabhav – All Dhatu Kshaya

Thus the mode of action of Virechana can be summarized in following points:-

- 1) It corrects the pratiloma gati of vayu, thus correcting the lakashanas caused by it like shotha, hrillas, chhardi,
- 2) It increases medodhatwaagni by and depletion of Aama and Kleda by Pradeepana karma .
- 3) It acts as an Aptarpak chikitsa on a santarpan janya vyadhi- Madhumeha and its complications.
- 4) Removal of excessive ambu one of the Duhsya in Madhumeha, thus reducing bahudrava Shlehsma and drava adhikyata expected in vitiated pitta in Diabetic nephropathy.

Aim

To Study the effect of Trayushnadi Gutika with and without Virechan in DM Nephropathy.

Primary Objective:- To Compare the effect of Trayushnadi Gutika with and without Virechan in DM Nephropathy.

Objective:- To study the Samprapti and management of DM Nephropathy.

Null Hypothesis (H₀):- The effect of Trayushnadi Gutika with or without Virechan by Abhyadi Modak is same in Pramehjanya updrav (Diabetic Nephropathy).

Alternate Hypothesis (H₁):- Trayushnadi Gutika is **more effective with virechan** by Abhyadi modak as compared to without virechan in Pramehjanya updrav (Diabetic Nephropathy).

METHODOLOGY

Randomized Comparative Clinical Study was done.

1. Screening of patients done as per the exclusion and inclusion criteria. Two groups –
Group A- Virechan (Snhepaan-Katu Tail) followed by Trayushnadi gutika intake Group
B- Trayushnadi Gutika intake without Virechan
2. Total duration of study -90 days, with follow up every week (1st 2nd 3rd 4th 5th 6th 7th 8th 9th
10th 11th 12th 13th)
3. Sample size -25 in each group
4. Final assessment at the end of the treatment with Statistical assessment was produced.

3) Samprapti vighatan

1) Abhaydi modak^[8]

The properties and action of Abhaydi Modak can be summarized as below:-

Veerya-Ushna

Rasa-Katu, Tikta

Vipaka-Madhur

Guna-Laghu, Ruksh, Teekshana

Karmukta-Virechak, Mehghna, Pleehaghna

Samprapti bhang In Prameha- Pitta Virechana, Agnimaandya Naashak, Rasayana karma of Abhaydi Modak helps in improving the prognosis of Prameha and its complications. It has significant result in Vata janya disease which makes its implementation in Vataja Prameha very useful. Hence the above useful properties of Abhaydi Modak can be implemented in treating the patients of Prameha.

2) Trayushnadi gutika^[9]

The properties and action of Trayushnadi Gutika can be summarized as below:-

Veerya- Ushna, Klednaashak,

Rasa- Katu Tikta

Guntah- Laghu and Ruksh

Doshghnata- Vata and Kapha shaamak

Karmukta- Mootrashodhak and Mootravirechniya, Anulomak

Samprapti bhang In Prameha

- 1) Agni Prabhav- Jathraagnimaandya naashak, Medaagni naashak
- 2) Mootrashodhak and Mootravirechniya Thus probable Mootrashodhak and Mootravirechniya action in Diabetic Nephropathy patients can be inferred from its Properties which will give significant results.

Hence the above useful properties of Trayushnadi Gutika can be implemented in treating the patients of Prameha.

Statistical tests^[10]

For within the group comparison (Intra- Group Comparison)

1. For Subjective Parameters: Wilcoxon matched-pairs signed-ranks test
2. For Objective Parameters: Student's paired t test

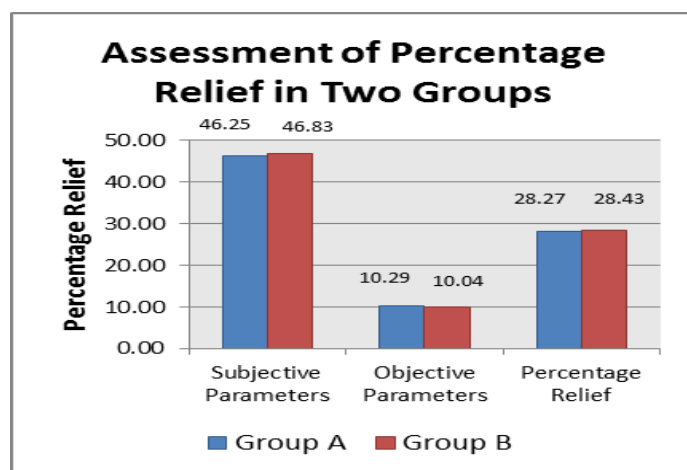
For between the groups comparison (Inter- Group Comparison)

1. For Subjective Parameters: Mann – Whitney test
2. For Objective Parameters: Unpaired t test

For overall assessment of therapy: (Discrete data)

Chi – Square test of independence was applied.

P value - 0.05 was considered significant



RESULT

Overall assessment of therapy in percentage

As shown in the Chart above the Overall effect of therapy given in both groups was calculated in percentage.

Subjective parameters

- In Group A, there was a change, here improvement of 46.25%.
- In Group B, there was a change, here improvement of 46.83%.

Objective parameters

- In Group A, there was a change, here improvement of 10.29%.
- In group B, there was a change, here improvement of 10.04%.

Total percentage relief

- In Group A, total effect of therapy in terms of percentage relief was 28.27%.
- In Group B, total effect of therapy in terms of percentage relief was 28.43%, which was slightly better as compared to Group A.

CONCLUSION

Based upon the results of the study displayed in the form of tables and charts and critically discussed in the previous chapter, following conclusions are drawn –

- *Diabetic Nephropathy* is more common in 61-65 years age group (28%).
- Males and Female are equally affected with *Pramehajanya updrava i.e. Diabetic Nephropathy* here 50% each.
- Patients with *Diabetic Nephropathy* mostly have Mandaagni (96%) and Krura Koshtha (66%).
- *Diabetic Nephropathy* occurs mostly in people affected with stress due to professional jobs (42%) followed by Housewives (38%).
- Mostly *Pitta-Vataja prakruti* patients (40%) were found suffering from *Diabetic Nephropathy* followed by *Vaat-pittaj prakruti* patients (38%).
- Patients with *Diabetic Nephropathy* mostly have Madhur Rasa Saatmya (76%).
- *Diabetic Nephropathy* patients mostly were of *Madhyama sattva* (40%) followed by *Heena sattva* (38%).
- On applying appropriate statistical tests of significance, Objective parameters which are Sr. Creatinine, ESR, HbA1c, Urine Albumin And Microalbuminuria showed significant changes after the treatment in both the groups.
- On applying appropriate statistical tests of significance, Subjective parameters i.e signs and symptoms which are Kshudha Alpata, Daurbalya, Pada shotha, Panduta in both the group showed significant Change here, reduction after the treatment.

- Though both the groups had changes in Subjective and Objective Parameters, they had similar results when compared to each other.
- Thus the conclusion can be drawn even without Virechan, Trayushnadi gutika has effect on diabetic Nephropathy even without Virechan.
- Thus the Null Hypothesis (H₀) cannot be rejected as Trayushnadi Gutika had effect in both the groups showing better result in Group B
- (28.43%) with a very minor difference over Group A (28.27%).
- Also, from the literary review, we can conclude that, there are physiological changes in the patients of Diabetic Nephropathy. An Ayurvedic Treatment using Trayushndi gutika is effective in samprapti Bhang of Diabetic Nephropathy.
- On applying appropriate statistical tests of significance, Objective parameters and Objective showed significant changes after the treatment in both the groups.
- Though both the groups had similar result when compared to each other. Thus the conclusion can be drawn even without Virechan, Trayushnadi gutika has effect on diabetic Nephropathy even without Virechan.
- Thus the Null Hypothesis cannot be rejected as Trayushnadi Gutika had effect in both the groups showing better result in Group B with a very minor difference.
- Also, from the literary review, we can conclude that, there are physiological changes in the patients of Diabetic Nephropathy. An Ayurvedic Treatment using Trayushndi gutika is effective in samprapti Bhang of Diabetic Nephropathy.

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