CLINICAL STUDY TO ASSESS THE EFFICACY OF *MUTRAVIRAJANEEYA MAHAKASHAYA* IN *AVILAMUTRATA* OF *PRAMEHA* (TYPE 2 DIABETES MELLITUS)

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ABSTRACT

Prameha, has been described in Ayurvedic literatures as a disease to be diagnosed at the level of *mutra* with the *samanya lakshanas* of *prabhootamutrata* and *avilamutrata*. *Avilamutrata* means *samala mutra* which is due to the presence of the *avayavas* of *dushyas* which take part in the *samprapti* of *prameha*. Acharya Charaka in *Shadvirechanasataasriteeyam adhyayam* has mentioned *Mutravirajaneeya Mahakashaya,* the action of which is targeting on *mutra* was utilized in the management of *Avilamutrata* of *Prameha.* The term *virajana* means providing colour to something. Hence, *Mutravirajaneeya Mahakashaya* will be capable of correcting the colour, i.e, in bringing back the *prakrta varna* to *mutra*.

Keywords – *Mutra, Prameha, Avilamutrata, Mutravirajaneeya Mahakashaya*

INTRODUCTION

Mutra has been mentioned with utmost importance as a biological fluid formed as the ultimate end product of various *agni vyapara* in the body. Right from the ancient period, various references are available, pointing towards the diagnosis of diseases, by examining the various characters of *mutra*. *Prameha* is one among them, which is described throughout the Ayurvedic literatures as the disease arising out of different clinical presentations at the level of *mutra*. The *samanya lakshana* of *prameha* is told to be *prabhootamutrata* and *avilamutrata* which arises as a result of the *samprapti* occurred priorly. Acharya Charaka in *Shadvirechanasataasriteeyam adhyayam* has mentioned *Mutravirajaneeya Mahakashaya,* the action of which is targeting on *mutra* was utilized in the management of *Avilamutrata* of *Prameha* (Type 2 Diabetes Mellitus).

Aavila mutrata

आविलं समलम्| [1] (*Su.Ni – 6/6 – Nibandasangraha*)

The word meaning of *Aavilam* is *Samalam*. In this context, *Aavila Mutrata* refers to *samala mutra*. It is due to,

तत्राविलत्वं मूत्रस्य प्रमेहदूष्याणां मेदोरक्तमांसमज्जाशुक्रोदकवसालसीकौजसां क्वचिदेव प्रमेहे कस्यचिदेव दूष्यस्यावयवमिश्रीभावात्| [2] (*Su.Ni – 6/6 – Nyayachandrika*)

This characteristic feature of urine is because of the combination of the *avayavas* of *medo mamsadi dushyas* with *mutra*.

A Note on *Mutravirajaneeya Mahakashaya*

The term '*virajana*' means providing colour to something. Hence, *Mutravirajana* means providing colour to *Mutra*, a *malabhava* formed in the *sareera* as a result of the various *Agni Vyapara* occurring to the ingested *Ahara*.

Mutravirajaneeya consists of the words **'*Mutravirajana*'** and **'*eeya*' pratyaya**

'*Mutravirajana*'

- ✓ पुरीषस्य विरजनं दोषसम्ब्धनिरासं करोति इति पुरीषविरजनीय:। एवं मूत्रविरजनीये व्याख्येयम्। [3] (*Chakrapani – Cha.su – 4/7*)
  The drugs which do the colouring of *Pureesha* as well as the expulsion of unwanted doshas through it is known as *Pureesha virajaneeya*, the same can be inferred in case of *Mutra* also.
- ✓ मूत्रं नयति विरागं अथवा मूत्रस्य दोषसम्बन्धनिरासं करोति नाम प्राकृत वर्ण स्थापयति मूत्र विरजनीयम्। [4] (*Ayurveda Sabdakosham*)

The drugs which provide normal colour to *mutra* after correcting the pathology occurred, i.e, after removing the mutual interaction between the doshas which served for the vikrita varna.

- ✓ दोष दुष्टं मूत्रं विरन्जयित्वा प्रकृतौ स्थापयति तद् मूत्रविरजनीयम्| [5] (Internet source)

- ✓ The word विरज means निर्मल (*Sabdakalpadruma*)

'eeya' pratyaya

- ✓ एतच्च ईयप्रत्ययान्तत्वादिना बहुभेदकथनं वैचित्र्येण ग्रन्थस्य पुष्कलाभिधानताकरणार्थम्| एतच्च शास्त्रेऽवश्यं कर्तव्यम्| [6] (*Cha.Su – 4/8 – Chakrapani*)

- ✓ Terminologies like, *'eeya', 'hara', 'upaga'*, etc are used differently in the context of *Mahakashayas* in order to promote the *Pushkalabhidana* (a *tantra guna*) of the *grantha*.

Drugs of *Mutravirajaneeya Mahakashaya*[7]

It contains a group of 10 drugs with *Mutravirajaneeya Karma*. They include **Dhataki, Priyangu, Madhuka, Padma, Pundareeka, Satapatra, Kumuda, Utpala, Sougandhika** and **Nalina.**

Sl.No	Sanskrit Name	Latin Name	Family	English Name
	Table No. 1 Table showing the list of ten *Mutravirajaneeya Dravyas*[8]			
1	**Dhataki**	Woodfordia fruticosa	Lytharacea	Fire flame bush
2	**Priyangu**	Callicarpa macrophylla	Verbenaceae	Beauty berry
3	**Madhuka**	Glycyrrhiza glabra	Fabaceae	Liquorice
4	**Padma**	Nelumbo speciosum	Nelumbonaceae	Lotus
5	*Pundareeka*	Nelumbo nucifera	Nelumbonaceae	White flowered lotus
6	*Satapatra* – In place of *Satapatra*, the quantity of *Padma* was doubled.			1000 petalled lotus
7	**Kumuda**	Nymphea alba	Nymphaceae	White water lily

8	*Utpala* – *Neelotpalam* was used instead of *Utpala*	Neelotpalam - Monochoria hastate	Neelotpalam - Pontederaceae	Neelotpalam - Arrow leaf pondweed
9	*Sougandhika*	Nymphea rubra	Nymphaceae	Red flowered lily
10	*Nalina* – The quantity of *Kumuda* was doubled			

Table No. 2 Table showing the properties of ten *Mutravirajaneeya Dravyas*[9]					
Sl.No	**Drug**	**Rasa**	**Guna**	**Virya**	**Vipaka**	**Dosha Karma**
1	*Dhataki*	*Kashaya*	*Laghu, Rooksha*	*Seeta*	*Katu*	*Kaphapitta hara*
2	*Priyangu*	*Tikta, Kashaya, Madhura*	*Guru, Rooksha*	*Seeta*	*Katu*	*Kapha pittahara*
3	*Madhuka*	*Madhura*	*Guru, Snigdha*	*Seeta*	*Madhura*	*Tridoshahara*
4	*Padma*	*Kashaya, Madhura, Tikta*	*Laghu, Snigdha, Picchila*	*Seeta*	*Madhura*	*Kaphapittahara*
5	*Pundareeka*	*Kashaya, Madhura, Tikta*	*Laghu, Snigdha, Picchila*	*Seeta*	*Madhura*	*Kaphapittahara*
6	*Satapatra*	*Kashaya, Madhura, Tikta*	*Laghu, Snigdha, Picchila*	*Seeta*	*Madhura*	*Kaphapittahara*
7	*Kumuda*	*Madhura, Kashaya, Tikta*	*Laghu, Snigdha, Picchila*	*Seeta*	*Madhura*	*Tridoshagna*

8	*Utpala*	*Madhura, Kashaya, Tikta*	*Laghu, Snigdha, Picchila*	*Seeta*	*Madhura*	*Tridoshagna*
9	*Sougandhika*	*Madhura, Kashaya, Tikta*	*Laghu, Snigdha, Picchila*	*Seeta*	*Madhura*	*Tridoshagna*
10	*Nalina*	*Madhura, Kashaya, Tikta*	*Laghu, Snigdha, Picchila*	*Seeta*	*Madhura*	*Tridoshagna*

OBJECTIVE

To assess the efficacy of *Mutravirajaneeya Mahakashaya* in *Avilamutrata* of *Prameha* (Type 2 Diabetes Mellitus).

MATERIALS AND METHODS

- ✓ *Mutravirajaneeya Mahakashaya* is mentioned in Charaka Samhita Sutrasthana 4th chapter – *Shadvirechana sataasriteeyam adhyayam.*
- ✓ The 10 drugs of *Mutravirajaneeya Mahakashaya* were collected and prepared as medicine in the form of concentrated *Kashaya*, procured from a GMP Certified Company.
- ✓ Subjects fulfilling the inclusion criteria with respect to age, irrespective of gender, caste, religion and socio-economic status who approached the OPD of Government Ayurveda Medical College and Hospital Mysuru, Hi-tech Panchakarma Hospital Mysuru and Charaka Government Ayurveda Post graduation centre Mysuru have been incorporated for the study.
- ✓ **Study Design -** The present study was an open – labelled, prospective interventional study to evaluate the efficacy of *Mutravirajaneeya Mahakashaya* in *Avilamutrata* of *Prameha* with Pre and Post Test Design.
- ✓ **Sampling Method -** Purposive Sampling
- ✓ **Sample Size** - Minimum of 20 subjects with *Avilamutrata* of known case of *Prameha* (Type 2 Diabetes Mellitus).
- ✓ **Sample collection Method -** Data was obtained from a minimum of 20 subjects of *Avilamutrata* with Type 2 Diabetes Mellitus.

Inclusion criteria

- Diagnosed cases of Type 2 DM falling in the age group of 40 – 60 years were selected for the study.

- Patients fulfilling the diagnostic criteria were selected for the study.

Exclusion criteria

- Patients of Type 1 Diabetes Mellitus.

- Pregnant and lactating women.

- Patients with any other systemic ailments which interferes with the study.

Diagnostic criteria

1. Turbidity & altered color on physical examination of urine. Increased specific gravity of urine.

2. Fasting Blood Sugar ≥126mg/dl & ≤170mg/dl.

3. Post Prandial Blood Sugar ≥181mg/dl & ≤ 230mg/dl.

4. Urine Sugar ≥ 0.5%.

Investigations

- Fasting Blood Sugar

- Post Prandial Blood Sugar

- Urine sugar

Assessment criteria

Internal administration of 15ml of *Mutravirajaneeya Mahakashaya* diluted with 45ml of lukewarm water twice a day one hour before food for all 30 consecutive days of intervention.

Objective criteria

1. **Fasting Blood Glucose Level**
   a. Below 126 mg/dl – Grade 0
   b. 126mg/dl – 140mg/dl – Grade 1
   c. 141mg/dl – 155mg/dl – Grade 2
   d. 156mg/dl – 170mg/dl – Grade 3
   e. Above 170mg/dl – Grade 4

2. **Post Prandial Blood Glucose Level**
   a. Below 181mg/dl – Grade 0
   b. 181mg/dl – 195mg/dl – Grade 1
   c. 196mg/dl – 210mg/dl – Grade 2
   d. 211mg/dl – 225mg/dl – Grade 3
   e. Above 225mg/dl - Grade 4

3. **Urine Sugar**
   a. Green – Negative – Grade 0
   b. Yellow – green – < 0.5% glucose – Grade 1
   c. Greenish yellow – 0.5-1% glucose – Grade 2
   d. Yellow – 1-2% glucose – Grade 3
   e. Orange to brick red – > 2% glucose – Grade 4

4. **Urine Analysis using dipstick**

Urine Specific gravity

a. 1.000 – Blue - Grade 0

b. 1.005 – Bluish Green - Grade 1

c. 1.010 - Pale Green - Grade 2

d. 1.015 - Light Green - Grade 3

e. 1.020 – Yellowish Green - Grade 4

f. 1.025 – Greenish Yellow - Grade 5

g. 1.030 – Yellow – Grade 6

Urine pH level

a. 5 – Orange - Grade 1

b. 6 – Yellow - Grade 2

c. 6.5 – Brownish Yellow – Grade 3

d. 7 – Light Green – Grade 4

e. 8 – Green – Grade 5

f. 9 – Blue – Grade 6

Urine Ketones

a. > 0.5 mg/dl - Very light pink – Grade 0

b. 0.5 mg/dl – Light pink – Grade 1

c. 1.5 mg/dl – Pink – Grade 2

d. 3.9 mg/dl – Little dark pink – Grade 3

e. 10 mg/dl – Dark pink – Grade 4

Urine protein

a. Negative - Yellow – Grade 0

b. Trace - Yellowish Green – Grade 1

c. 0.3mg/dl - Greenish Yellow – Grade 2

d. 1mg/dl - Light Green – Grade 3

e. 3mg/dl - Olive Green – Grade 4

f. 10mg/dl - Green – Grade 5

5. **Urine Turbidity**

a. Clear – Grade 0

b. Slightly Cloudy – Grade 1

c. Cloudy – Grade 2

d. Opaque – Grade 3

6. **Urine Colour on Physical Examination** – the urine colour is graded from -2 to 5 based on standard colour chart graded on increasing intensity of colour. Grade 0 is taken as the normal colour of urine.

Statistical analysis

Table No. 3 Table showing the methods of Statistical analysis of the obtained data	
Descriptive statistics	**Inferential statistics**
Frequency	Chi – square test
Percentage	

OBSERVATIONS AND RESULTS

FASTING BLOOD SUGAR (FBS)

In the present study, all the subjects had increased fasting blood glucose level before treatment which showed no significant reduction after treatment.

Table No: 4 Findings of FBS before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		**Frequency**	**Percentage**	**Total**
Grade 4	BT	1	5%	3(7.5%)
	AT	2	10%	
Grade 3	BT	13	65%	21 (52.5%)
	AT	8	40%	
Grade 2	BT	5	25%	9 (22.5%)
	AT	4	20%	
Grade 1	BT	1	1%	7 (17.5%)
	AT	6	30%	

Result – The results were statistically non - significant with $p – value$ 0.157

POST PRANDIAL BLOOD SUGAR (PPBS)

In the present study, all the subjects had increased post prandial blood glucose level before treatment which showed no significant reduction after treatment.

Table No: 5 Findings of PPBS before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		Frequency	Percentage	Total
Grade 4	BT	3	15%	11 (27.5%)
	AT	8	40%	
Grade 3	BT	10	50%	13 (32.5%)
	AT	3	15%	
Grade 2	BT	5	25%	11 (27.5%)
	AT	6	30%	
Grade 1	BT	2	10%	5 (12.5%)
	AT	3	15%	

Result – The results were statistically non-significant with $p – value$ 0.096

URINE SUGAR

In the present study, all the subjects had increased urine sugar level before treatment which showed no significant reduction after treatment.

Table No: 6 Findings of Urine sugar before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		Frequency	Percentage	Total
Grade 4	BT	11	55%	22 (55%)
	AT	11	55%	
Grade 3	BT	8	40%	13 (32.5%)
	AT	5	25%	
Grade 2	BT	1	5%	4 (10%)
	AT	3	15%	

| Grade 1 | BT | 0 | 0% | 1 (2.5%) |
| | AT | 1 | 5% | |

Result – The results were statistically non-significant with *p – value* 0.442

URINE COLOR

In the present study, all the subjects had variation in urine color before treatment which came back almost to normalcy after treatment.

Table No: 7 Findings of Urine color before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		**Frequency**	**Percentage**	**Total**
Grade -1	BT	0	0%	8 (20%)
	AT	8	40%	
Grade 0	BT	0	0%	3 (7.5%)
	AT	3	15%	
Grade 1	BT	4	20%	13 (32.5%)
	AT	9	45%	
Grade 2	BT	15	75%	15 (37.5%)
	AT	0	0%	
Grade 3	BT	1	5%	1 (2.5%)
	AT	0	0%	

Result – The results were statistically highly significant with *p – value* 0.001

URINE TURBIDITY

In the present study, all the subjects had variation in urine turbidity before treatment which came back almost to normalcy after treatment.

Table No: 8 Findings of Urine turbidity before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		**Frequency**	**Percentage**	**Total**
Grade 0	BT	0	0%	8 (20%)
	AT	8	40%	
Grade 1	BT	0	0%	3 (7.5%)
	AT	3	15%	
Grade 2	BT	4	20%	13 (32.5%)
	AT	9	45%	
Grade 3	BT	15	75%	15 (37.5%)
	AT	0	0%	
Grade 4	BT	1	5%	1 (2.5%)
	AT	0	0%	

Result – The results were statistically highly significant with $p – value$ 0.001

URINE SPECIFIC GRAVITY

In the present study, all the subjects had variation in urine specific gravity before treatment which showed no significant change after treatment.

Table No: 9 Findings of Urine specific gravity before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		**Frequency**	**Percentage**	**Total**
Grade 1	BT	0	0%	1 (2.5%)
	AT	1	5%	
Grade 2	BT	3	15%	8 (20%)
	AT	5	25%	
Grade 3	BT	6	30%	17 (42.5%)
	AT	11	55%	
Grade 4	BT	7	35%	10 (25%)
	AT	3	15%	
Grade 5	BT	3	15%	3 (7.5%)
	AT	0	0%	
Grade 6	BT	1	5%	1 (2.5%)
	AT	0	0%	

Result – The results were statistically non-significant with $p – value$ 0.127

URINE pH

In the present study, all the subjects had variation in urine pH before treatment which showed no significant change after treatment.

Table No: 10 Findings of Urine pH before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		**Frequency**	**Percentage**	**Total**
Grade 1	BT	0	0%	1 (2.5%)
	AT	1	5%	
Grade 2	BT	3	15%	8 (20%)
	AT	5	25%	
Grade 3	BT	6	30%	17 (42.5%)
	AT	11	55%	
Grade 4	BT	7	35%	10 (25%)
	AT	3	15%	
Grade 5	BT	3	15%	3 (7.5%)
	AT	0	0%	
Grade 6	BT	1	5%	1 (2.5%)
	AT	0	0%	

Result – The results were statistically non-significant with $p – value$ 0.191

URINE PROTEIN

In the present study, all the subjects had variation in urine protein before treatment which showed no significant change after treatment.

Table No: 11 Findings of Urine protein before and after the treatment with *Mutravirajaneeya Mahakashaya*			
Grading		**Frequency**	**Percentage**	**Total**
Grade 0	BT	0	0%	1 (2.5%)
	AT	1	5%	
Grade 1	BT	1	5%	3 (7.5%)
	AT	2	10%	
Grade 2	BT	8	40%	20 (50%)
	AT	12	60%	
Grade 3	BT	6	30%	7 (17.5%)
	AT	1	5%	
Grade 4	BT	2	10%	6 (15%)
	AT	4	20%	
Grade 5	BT	3	15%	3 (7.5%)
	AT	0	0%	

Result – The results were statistically non-significant with $p - value$ 0.095

URINE KETONE

In the present study, all the subjects had variation in urine ketone before treatment which showed no significant change after treatment.

Table No: 12 Findings of Urine ketone before and after the treatment with *Mutravirajaneeya Mahakashaya*				
Grading		Frequency	Percentage	Total
Grade 0	BT	4	20%	9 (22.5%)
	AT	5	25%	
Grade 1	BT	12	60%	23 (57.5%)
	AT	11	55%	
Grade 2	BT	4	20%	7 (17.5%)
	AT	3	15%	
Grade 3	BT	0	0%	1 (2.5%)
	AT	1	5%	

Result – The results were statistically non-significant with $p-value$ 0.730

DISCUSSION

Mutravirajaneeya, the term is pointing towards providing colour to *mutra*. This implies that *mutra* is having *prakrta varna* and *vikrta varna* in its *physiology* and *pathology* respectively. Though the *prakrta varna* is not mentioned as such, references of different *vikrta varna* are explained in different diseases which itself point towards the fact that *mutra* itself is a yardstick or litmus test, which plays a pivotal role in representing the state of *sareera*.

Mutravirajaneeya Mahakashaya

Since the definition of *Mutravirajaneeya* says that these are the drugs capable of eliminating the *dosha sambanda*, i.e, capable of removing the pathology happened in order to excrete the *mutra* in its *prakrta varna*. Here, the word 'viraja' literally meaning providing colour, it is rather focusing on bringing out the *prakrta varna* by getting rid of the *malas*. Hence, *malas* here is symbolizing all those factors responsible for the creation of *vikrta varna* in *mutra*, a must to be acknowledged description because allocating 'varna' is a key function of *Pitta dosha*.

Rasa Panchaka of *Mutravirajaneeya* Drugs

A deductive study of each drug in this *mahakashaya* has been carried out by analysing the *rasa panchakas* of every drug, to arrive at a logic for the *virajana karma* exhibited by them. Henceforth, the *Rasa, Guna, Virya, Vipaka* and *Karma* of *Mutravirajaneeya Mahakashaya* have been discussed below.

Sl.No	Predominant *Rasa Panchaka*	Analysis	Interpretation
	Table No. 13 Table showing the Predominant *Rasa Panchakas* of *Mutravirajaneeya Mahakashaya* on analysis and interpretation		
1	*Rasa – Madhura, Kashaya, Tikta*	All the three predominant *rasas* reduce *pitta*, while *Kashaya* and *Tikta* reduces *kapha*.	Maintains the *prakrta varna* of *mutra*, i.e, reduces *aavila mutrata*.
2	*Guna – Laghu, Snigdha, Picchila*	These *gunas* are *pitta vardhaka*.	From the observation of the action of the *Kashaya*, it acts specially as *Pittasamana*, which is through their *rasa*, *virya* and *vipaka*.
3	*Virya – Seeta*	*Seeta virya* does *prasadana* of *pitta* and *rakta*	Maintains the *prakrta varna* of *mutra*, i.e, reduces *aavila mutrata*.
4	*Vipaka - Madhura*	Does *prasadana* of *pitta* and *rakta*	Useful in *Aavila mutrata*
5	*Karma - Tridoshaharatwa* and *Kapha – Pittaharatwa karma*	*Pittaharatwa* is the predominant *karma* observed.	From the observation of the action of the *Kashaya*, it acts specially as *Pittasamana*, which is through their *rasa*, *virya* and *vipaka*.

Probable Mode of Action of *Mutravirajaneeya Mahakashaya*

Sl.No	Observation	Analysis
	Table No. 14 Table showing the Probable Mode of Action of *Mutravirajaneeya Mahakashaya*	
1	Normalizing Urine Color	Due to the *Pittaharatwa karma* of *Mutravirajaneeya Mahakashaya*
2	Reduction in Urine Turbidity	Due to the *Pittaharatwa karma* of *Mutravirajaneeya Mahakashaya*
3	Slight Reduction in Urine pH	Due to the *Pittaharatwa* of *Mutravirajaneeya Mahakashaya*.
4	Slight Reduction in Urine specific gravity	Due to the *Kashaya rasa* and *laghu guna* of *Mutravirajaneeya Mahakashaya*.
5	Slight Reduction in Urine Ketone	Due to the *Kashaya rasa, laghu guna, pittahara* and *raktaprasadana karma* of *Mutravirajaneeya Mahakashaya*
6	Slight Reduction in Urine Protein	Due to the *Pittaharatwa* and *Rakta prasadana karma* of *Mutravirajaneeya Mahakashaya,*

CONCLUSION

Mutravirajaneeya Mahakashaya was effective in controlling the **Urine Color** and **Urine Turbidity** with high statistical significance of *p – value* **0.001.** A little reduction in Urine pH, Urine Specific gravity, Urine Ketone and Urine Protein were achieved. No significant reduction in the values of FBS, PPBS and Urine Sugar.

On a detailed analysis of this Kashaya, using the *Rasa panchakas* have shown to be extreme *Pitta samana* by the aid of 10 drugs possessing *Seeta virya*. It has been a finding from the above research work that, since these drugs are capable of doing *rakta – pitta prasadana, artava dushti* associated with *rakta pitta dushti* are also getting nullified. Therefore, this *kashaya* may be given in any conditions of *apana vaigunya* with associated *rakta – pitta dushti*.

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