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RESEARCH ARTICLE

Evaluation of the Therapeutic Potential of *Woodfordia fruticosa* (L.) Kurz. (*Dhataki Pushpa Churna)* and Cital Syrup in *Mutravaiwarnya*: A Randomized Clinical Study

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Abstract

Background: Abnormal color of urine can occur due to various physiological and pathological factors. The *Mutravaivarnya* (urinary discoloration) can be considered as main sign of UTI (Urinary Tract Infections) and other urinary disorders. Ayurvedic classics mention *Dhataki Pushpa* (*Woodfordia fruticosa* (L.) Kurz) in the *Mutravirajneeya Mahakashaya* (MVM). This *Kashaya* is a group of herbs that reverts abnormal color of urine to normal (SAT-F. 221- group of ten urinary depigmenting *Dravya*). **Aim:** To evaluate the effectiveness of the *Mutravirajneeya* Action (MVA) of *Dhataki Pushpa Churna* (DPC) against Cital syrup in patients suffering from abnormal color of urine *i.e., Mutravaiwarnya* (MV) is the aim of present study. **Methods:** The clinical study was performed on a group of randomly selected 60 patients from age group of 18-60 years and of either sex, presenting signs and symptoms of MV. Patients were categorized into two groups, Group A (Trial group) and Group B (Control group). Group A was given DPC where as Group B was treated with Cital syrup (Disodium hydrogen citrate 1.37gm/5ml syrup). Treatment was given for 7 days and follow up of patients was taken on 3rd and 8th day. The urine color was observed and compared with Pantone Color Scale 101 (PCS) which is standard pale yellow. **Result:** Overall effect of DPC in Group A on MV was 86.67% and of Cital syrup in Group B was 63.33%. Highly significant results were noted. Simultaneously significant difference was observed in PCS between mean differences of Group A (6.033) and Group B (4.440) reading. **Conclusion:** Apart from MV; DPC was found to be more effective in symptoms like *Sadaha Mutrata* (Burning micturition) and *Sashul mutrata* (Painful micturition). It can be concluded that DPC shows highly significant results in subjective as well as objective parameters of MV.

Major Findings: The perspective of DPC which is not previously addressed in any research article, is dealt in present comparative clinical study for *Mutravaiwarnya* against Cital syrup, a well-known urine alkalizer. Overall effect of DPC in Group A on MV was 86.67% and of Cital syrup in Group B was 63.33%. In Group A, mean decrease in PCS was 6.03 and in Group B, it was 4.40. This suggests that PCS has decreased more in Group A than in Group B. Thus, DPC shows highly significant results in subjective as well as objective parameters of MV.

Keywords: Abnormal Urine Color, *Dhataki Pushpa Churna, Mutravaiwarnya, Mutravirajneeya Mahakashaya,* Pantone Color Scale, *W. fruticosa* (L.) Kurz

Abbreviations: *Mutravirajneeya Mahakashaya*- MVM; *Mutravirajneeya* Action- MVA; *Dhataki Pushpa Churna*- DPC; *Mutravaiwarnya*- MV; Pantone Color Scale 101- PCS; Intestinal Microbiota- IM

1. Introduction

Urine is an important metabolic product; production and excretion of which is necessary to maintain the homeostasis of the body[1]. Abnormal urine color may be caused by increased *Pitta dosha*, urine infection, any disease or disease condition, medications or the food consumed[2]. The discoloration of urine

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can range from orange color to pink, brown, black and even blue color indicative of various disease conditions[3]. In *Ayurvedic* texts *Mutravaiwarnya* (MV) or abnormal color of urine is mentioned as a sign of different diseases such as *Jwara* (Fever), *Kamla* (Jaundice), *Mutrakruchhra* (Dysuria), *Prameha* (Diabetes, Polyuria)[4-7]*etc*. The persistent abnormal color of urine can become a cause of anxiety in an individual. MV is not mentioned as a disease in classical texts, but list of drugs, acting on it are mentioned in *Mutravirajaneeya Mahakashaya* (MVM)[4-7]. *Charaka* has mentioned MVM in chapter 4th of *Sutrasthana* where a group of 10 herbs, which has the property to restore normal color of urine is mentioned[8]. There is lack of safe and effective remedy for the correction of conditions like urine discoloration. Urine can be an early indicator of underlying health conditions such as infections, liver disorders, kidney diseases, or metabolic disorders. Addressing this issue can help in early diagnosis and treatment. Treatment using *Ayurvedic* drugs can be an alternative solution to provide effective treatment for MV. This can help in providing breakthrough in effective management of abnormal urine color and conditions underlying this sign.

Woodfordia fruticosa (L.) Kurz is a herbal plant that belongs to the family *Lythraceae*. This plant is widely distributed throughout the tropical and subtropical regions of India, Sri Lanka, China, Malaysia, Indonesia, Japan and Pakistan[9]. The flowers are consider to have great therapeutic activity such as antimicrobial, hepatoprotective, cardioprotective, antioxidant, anti-ulcer, immunomodulatory, anti-fertility and anti-tumour due to presence of several phytochemicals like tannins, flavonoids, glycosides and polyphenols[9].

The pharmacological activities of *W. fruticosa* plant is also mentioned in the literature of *Ayurveda, Unani* and other traditional systems of medicine. In *Ayurveda* scriptures *Dhataki Pushpa* is one of the contents of MVM and has taste as *Kashaya* (astringent) and *Tikta* (bitter), *Katu Vipaka (*resultant effect*)* and *Sheeta Veerya* (cold potency) which can aid in alleviation of *Pitta Dosha;* which may cause MV and *Mutradaha* (burning micturition)[10]. *W. fructicosa* (L.) Kurz flowers have previously been studied for their anti-microbial and anti-inflammatory activity analytically; *in vitro* and *in vivo* however no study is yet done to assess its effect on the urine discoloration or urinary tract infections[11-13]. This study is a unique study which addresses undefined aspect of DPC in *Nighantu granthas*. Previous works related to urinary complaints includes interventions with multiple herbo-mineral drugs and combinations. Whereas in present study only herbal drug is used as intervention for the assessment of MVA of DPC verses Cital syrup.

2. Materials and Methods

2.1 Materials

2.1.1 Trial Drug

Woodfordia fruticosa (L.) Kurz, DPC mentioned in MVM of *Charak Samhita* in *Shadvirechanashatashritiya Adhyaya* was used for treatment purpose of MV. The raw drug *i.e.,* flowers (Figure 1) were authenticated at research laboratory and QC department of the institute. The drug was administered in the dose of 1gm twice daily for the period of 7 days. (Acc. to API dose of *Dhataki* is 3 to 6 gm, but to prevent property of *Dhataki* to induce *Mada* only 1gm of DPC was used twice a day).

2.1.2 Control Cital Syrup

This sugar free syrup having main content as Di sodium hydrogen citrate (1.37mg/5ml) was used in control group for comparison of effects. The syrup of INC-Indoco Remedies Limited Company was administered in the patients in dose of 5 ml twice a day for the period of 7 days[14].

2.2 Methodology

2.1.1 Clinical Study

The Clinical study was approved by the Institutional Ethics committee (AY/PG/116/2019-2020) and



Figure 1. **(a)**. Dhataki pushpa Churna. **(b)**. *W. fruticosa* (L.) Kurz dried flowers.

registered in Clinical Trial Registry of India (CTRI/2020/12/030023) before the commencement of study. After screening of the patients meeting the selection criteria, patients were categorized into two groups of 30 patients each, Group A (Trial group) and Group B (Control group). Randomization was done as per enrolment of patients in odd and even numbers. Simple random sampling method was used for randomization. Group A was given DPC whereas Group B was treated with Cital syrup. Medicine was given for 7 days and follow up of patients was taken on 3rd and 8th day. On both the follow-ups urine color was compared with the PCS. The difference in color of the urine was noted along with the associated symptoms.

2.1.2 Study Population

The screened patients who showed MV maximum up to 7 days with mild to moderate severity and as chief complaint along with increased status of *Pitta Dosha* and meeting the inclusion criteria were enrolled in study with written informed consent.

2.1.3 Patient Selection

Clinical study was performed on a group of randomly selected 60 patients with the complaint of MV, attending the OPD section of the *Kayachikitsa* department of the hospital attached to institute. Patients irrespective of gender, religion and socio-economic class between 18-60 years of age having deviation from normal pale-yellow color of urine along with increased status of *Pitta Dosha*, were included in the study. Patients suffering from BPH (Benign Prostatic Hypertrophy), CKD (chronic kidney disease), diabetes (*Prameha*), patients on AKT (Anti-Kochs Treatment), menstruating women's, patients suffering from other serious or chronic conditions, urine infection and continuously on medication for more than a month were excluded.

2.1.4 Sample Collection and Testing

Patients midstream clean catch urine specimen was collected and observed for its color in CCL and matched with PCS 101.

2.1.5 Criteria for Assessment

The assessment of urine discoloration was done using the PCS[15]. This color scale is part of Pantone color matching system for the standardization and comparison of different colors. The Pantone scale 101(Figure 2) is used for standardized pale-yellow color matching the normal pale-yellow color of urine. Thus, it was chosen as matching criteria for observing urine samples of patients before and after the intervention. A specially prepared case record form was used to collect the data. The associated complaints (signs and symptoms) of *Mutrashula* (pain during micturition), *Mutradaha* (burning micturition), *Krute-api Akrutasangyata* (even after micturition feeling persists as if not done) were assessed using the duly filled case record forms.

2.1.6 Study Setting

The study was conducted in *Kayachikitsa* OPD and pathology lab CCL of the institute.

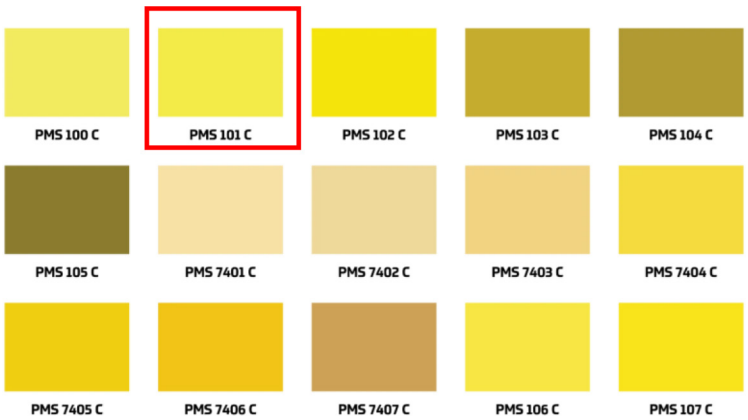


Figure 2. Standardized pantone color scale 101.

2.1.7 Suggestions

A common advise to all the patients was given, which includes following *aahar, vihaar* and *achaar* (behaviour).

2.2.8 Pathya

Ushnodaka, Narikel Jal, Raktashaali, Kushmand etc. are *Pathyakara Aahar* related to *Mutravaha Srotasa.*

2.2.9 Apathya

One should avoid *Ati Dravya* (very watery), *Katu* (pungent), *Tikshna* (penetrating like alkalis), *Amla* (sour), *Lavana* (salt), *Ati Madyapana* (excessive alcoholic drink). Due to consumption of such *Aahar* there is vitiation of *Pitta Dosha*, which results into diseases related to *Mutravaha Srotas.*

2.2.10 Lifestyle Changes

One should avoid *Trishna Nigrahan* (suppression of thirst or non-intake of water), *Mutra Nigrahan* (Suppression of micturition), *Aatapa Sevan* (exposure to excessive sunlight), *Ati Vyavaya* (Excessive sexual intercourse).

3. Results

The clinical study was completed in 60 patients. There was no drop out. Important findings regarding demographic variables like sex, age, religion, diet and *Prakruti* are listed in Table 1. It was found that according to gender maximum patients were females (85%), the greatest number of patients belongs to Muslim religion (48.33%). Maximum numbers of patients (78.33%) were used to consuming mixed (vegetarian and non-vegetarian) type of diet. It was also noted that patients reported in study showed *Pitta-kapha* dominant *Prakruti* (Table 1).

According to age maximum number of patients (n= 25) were from the age group of 28-38 years and minimum number was (n= 5) from the age group of 48-60 in both Group A and Group B (Table 2).

After taking treatment for 7 days, the patients from both the groups experienced significant relief in signs and symptoms as shown in (Table 3). *Sadah Mutrapravartana* (burning micturition) symptom showed maximum result in both the groups *i.e.* 89.66% and 80.77% in Group A, Group B respectively. Average % relief observed in Group A was 82.83%, which is better as compared to Group B., 65.19% (Table 3).

MV was present in all 60 patients on day 0 and persisted in 4 and 11 patients on day 8 in Group A and Group B respectively. Percent relief observed was 86.7% in Group A, 63.3% in Group B (Figure 3).

In Group A, *Sadahmutrata* was present in 29 patients on day 0 and persisted in 3 patients on day 8. Percent relief observed was 89.7%. In Group B, *Sadahmutrata*

Table 1. Demographic data of 60 patients suffering from *Mutravaivarnya* in both groups

S. No.	Criteria	No. of Patients			Percentage		
		Group A	Group B	Total	Group A	Group B	Total
Gender							
1	Male	6	3	9	20	10	15
2	Female	24	27	51	80	90	85
Religion							
1	Buddhist	6	4	10	20	13.33	16.67
2	Hindu	11	10	21	36.67	33.33	35
3	Muslim	13	16	29	43.33	53.33	48.33
Diet							
1	Veg	8	5	13	26.67	16.67	21.67
2	Mix	22	25	47	73.33	83.33	78.33
Prakruti							
1	*Pitta Kapha*	24	22	46	80	73.33	76.64
2	*Vata Pitta*	6	8	14	20	26.67	23.33

Table 2. Age wise distribution of patients in both the groups

Si. No.	Age (yrs.)	No of Patients			Percentage		
		Group A	Group B	Total	Group A	Group B	Total
1	18 to 28	6	8	14	20	26.67	23.33
2	28 to 38	12	13	25	40	43.33	41.67
3	38 to 48	9	7	16	30	23.33	26.67
4	48 to 60	3	2	5	10	6.667	8.333
5	Total	30	30	60	100	100	100

Table 3. Percentage relief in subjective parameters of patients from both the groups

Si. No.	Symptoms	% Relief	
		Group A	Group B
1	*Mutra Vaiwarnya*	86.67	63.33
2	*Sadah Mutrapravartan*	89.66	80.77
3	*Sashul Mutrapravartan*	80	66.67
4	*Kruteapiakruta Sandnyata*	75	50
5	Avg. % relief	82.83	65.19

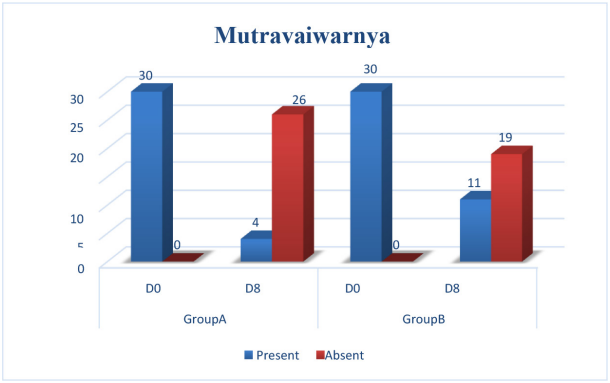


Figure 3. Comparison of effect of treatment (before and after) in Group A and Group B on *Mutravaiwarnya.*

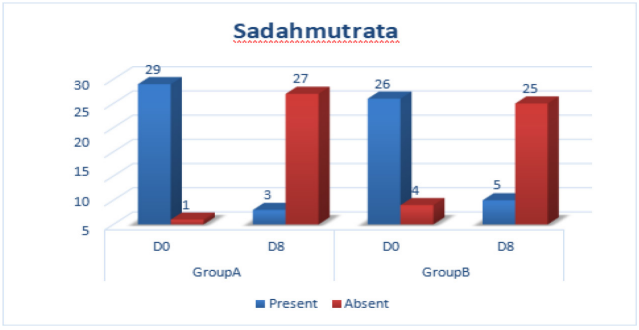


Figure 4. Comparison of effect of treatment (before and after) in Group A and Group B on *Sadahmutrata.*

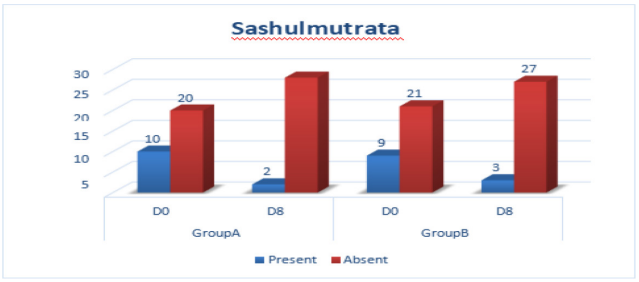


Figure 5. Comparison of effect of treatment (before and after) in Group A and Group B on *Sashulmutrata.*

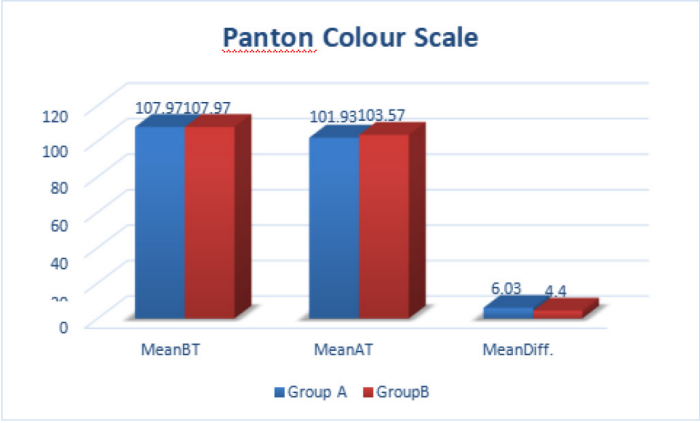


Figure 6. Comparison of effect of treatment (before and after) in Group A and Group B on Pantone color scale.

was present in 26 patients on day 0 and in 5 patients on day 8. Percent relief observed was 80.8%. (Figure 4).

In Group A, *Sashulmutrata* was present in 10 patients on day 0 and present in 2 patients on day 8. Percent relief observed was 80%. In Group B, *Sashulmutrata* was present in 9 patients on day 0 and present in 3 patients on day 8. Percent relief observed was 66.7%. (Figure 5).

It was observed that, mean decrease in PCS was, 6.03 in Group A and mean decrease in PCS was 4.40 in Group B. It suggests that PCS has decreased more in Group A than in Group B (Figure 6).

4. Discussion

The herb *W. fruticosa* (L.) Kurz contains tannins, flavonoids, anthraquinones, glycosides, and polyphenols, which contribute to its therapeutic properties[16]. The antibacterial activity of the crude methanol extract of *W. fruticosa* Kurz flower exhibited antibacterial activity at varied levels except against *Bacillus subtilis* and *Micrococcus flavus*. The extract was more active against Gram-negative bacteria as compared to Gram-positive[17]. These benefits are recognized in *Ayurveda, Unani*, and other traditional medicines, making the plant valuable in modern as well as herbal formulations.

The present clinical trial patients, randomly enrolled in both trial and control groups, were comparable in clinical characteristics and disease severity, which helped in diminishing the confounding factors at baseline. The sampling was of convenience as no previous data was available on the topic. This trial showed that DPC is more effective than Cital syrup in reduction of all the signs and symptoms MV, *Sashula mutrata, Sadaha mutrata,* and *Krute Api Akruta Sangnyata*. The data from the present study reflects that maximum number of patients were female (n=51); this might be due to higher prevalence of urinary tract infections in females than in males as results of various physiological, hormonal and anatomic factors[18]. As most of the females (87.23%) were also consuming mixed diet it can be stated that spicy, non veg and protein dominant diet may be one of the underlying causes for MV. Researchers have also proved that vegetarian diet may reduce the risk of urogenital tract diseases supporting the findings of the study[19]. Dominance of *Pitta Dosha* in *Pitta-kapha* dominant *Prakruti* was also noted as maximum (76.64%) which may have naturally caused dark yellow color of urine. *Pitta* dominant age (age group of 28-38 years) and perhaps suppression of urge for urine due to busy lifestyle; may have lead to maximum number of patients (n= 25). Overall effect of therapy after 7 days of treatment showed 82.83% relief in Group A, whereas in group B it was 65.19% relief. This clearly implies that DPC showed better relief in MV than Cital syrup. According to *Ayurveda*, the normal color of urine depends upon the healthy state of *Pitta Dosha*. Vitiation of *Pitta Dosha* can impart urine discoloration like dark yellow, reddish, black *etc*. As per the definition of MVA according to *Charak Samhita*, herbs belonging to MVM can help in bringing back normal pale-yellow color to urine[20]. Most of the herbs mentioned in MVM have properties like *Laghu, Sheeta* and taste as *Katu, Tikta Rasa* eliminating *Kleda* and *Pitta-kapha dosha* and thereby rendering normal color to urine[21]. As DPC has *Kashaya, Katu* taste and is of *Katu Vipak* and of *Sheet* (cold potency), it acts as *Daaha Shamak* and *Pitta Shamak dravya* proving it to be effective in *Sadaha Mutrata*[10]. According to *Ayurveda*, during the process of digestion and metabolism, *Prasad* (nutritive) and *Kitta* (excretory) parts are formed as end products. Through the further processing of *Kitta, Purish* (faeces) and *Mutra* (urine) are formed[22]. Almost all the *Nighantus* mentioned the drug *Dhataki*; causing *Mada* and elevating *Rakta-pitta* and *Atisar (dysentry)*. There is no direct mention about *Dhataki Pushpa* acting upon *Mutra* by any means[10]. According to *Charaka Samhita Dhataki* belongs to both *Mutravirajneeyagana* as well as *Pureesha Sangrahaniya Gana* (group of herbs imparting solidity to faecal matter)[23]. This is unique character of *Dhataki* which is established through this study. It acts on *Purishdharakala* which located in the *Pakwashaya* (intestinal) region, differentiates the *Mala* (*Purisha* or *Mutra*) and imparting the physiological properties to urine[24]. Thus DPC has proven to be effective in MV. Cital syrup (Disodium hydrogen citrate) works by decreasing the acidity of urine and helps the kidneys to get rid of uric acid, thereby preventing gout and kidney stones. It prevents certain kinds of bacteria from sticking to the walls of urinary tract and prevents infections[25,26].

The results of numerous studies confirm the need to take into account the Intestinal Microbiota (IM) influence, on the development of UTIs. IM correction can become a promising method in disease treatment and prevention. Positive results have been shown for

pro or prebiotics, FMT, and dietary interventions[27]. While the present study demonstrates the efficacy of DPC in managing MV, further research with larger sample size and patients having urinary tract infections can be conducted considering DPC as adjuvant medicine. Additionally, detailed pharmacological studies and antibacterial effect of DPC can help elucidate the precise mechanism of action of DPC. A key limitation of this study is the lack of biochemical study to support clinical outcomes. Moreover, DPC being an *Ayurvedic* formulation offers a cost-effective alternative with no proven side effects compared to conventional treatments like Cital Syrup, making it a promising medicine for broader clinical applications.

5. Conclusion

From the present study it can be concluded that oral intake of DPC is highly effective in treating MV as compared to control drug *i.e.*, Cital syrup (Disodium hydrogen citrate- an alkalizer). Group A administered with DPC showed better relief of 86.67% than Control drug which showed the relief of 63.33%. DPC is one such drug described in MVM acts on the *Pakwashaya* region having properties like *Kashay Rasa* and *Sheet Veerya* thus pacifies *Pitta dosha* and can help in reducing MV. Besides this, the plant is associated with various therapeutic and medicinal properties like antioxidant, antidiabetic, hypertensive, antifungal, antibacterial, anti-tumour, antiviral, antispasmodic and many more[9]. There is a need to relook and revaluate such formulations biochemically.

6. Author Contribution

PDB was responsible for designing the research protocol, writing the protocol, conducting the research, screening potentially eligible participants, extracting the data, and interpreting results. KPD was responsible for extracting and analyzing the data and formulating the tables and figures. VNJ was responsible for updating the research protocol, reference list and editing the final data. MVJ was responsible for designing the review protocol and interpreting the results. She contributed to final review of work and editing of the report. All authors have read and agreed to the published version of the manuscript.

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