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The Bio-Physiological and Socio-Economic Profile of Mutrashmari Patients

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Abstract-

in the suburbs of Jammu (Jammu & Kashmir State) to assess the comparative efficacy of Kullutha(K), Shwet Parpati(SP) – a mineral compound, singly as well as jointly i.e. K+SP, to evaluate their effects on a random sample of ten mutrashmari patients allocated to each in 2012-13. This article presents the ***bio-physiological and socio-economic profile of the sample patients*** as follows

Seventy percent of the cases were in the 3rd and 4th decades i.e. 21– 40 years age band. The gender ratio was : Female : Male **: :** 1: 1.72. Eighty-three percent were Hindu and the rest were Muslim. About 73.3 had rural background and the rest 26.7 % were from urban areas. Occupationally, 66.7 % belonged to the working class *viz.* farming (43.4%) and labour (23.3%). Seventy percent cases were either Higher Sec. pass are above and only 80.0 % of them were married. The lower socio-economic classes made up 63.0% of the sample. Only 16.6 % and 10. 0 % belonged to sthenic and pthisical categories respectively. The patients belonging to pthisical and other sicknesses were in the first stage i.e. curable and were on treatment. Addiction to tea was 100 %, tobacco chewing and smoking 70 % each and alcohol 66.7 % . Fifty per cent cases reported disturbed sleep while 46.7 % reported normal sleep. Fifty percent of the cases consumed

mixed diet i.e. the diet rich in fats, sodium, calcium etc which increases the chances of calcium salt crystallization. Majority (46.7 %) of the cases were having Adhyasana followed by 23.3 % having Visamasana. Madhura Rasa was dominant (90 %) in diet, followed by Katu Rasa (50.0 %). Manda Agni Bala and Sama Agni Bala were dominant in the cases. About 46.7 % cases were having Vata-Kaphaja Prakrti, followed by 30 % of Vata-Pitta Prakriti and 23.3 % of Kapha-Pitta Prakriti. Majority (46.7 %) of the cases were having adhyasana followed by 23.3 % having visamasana. Madhyama Kostha was the most predominant type (76.7 %), followed by Mridu (23.3 %). Patients were almost equally distributed into the three types of Ahara Prakriti. About 47 % of the cases fell in Avara Vyayama shakti category, 43.3 % in

Madhyama category, while only 10.0 % belonged to Pravara category. Only 10.0 % patients reported calculi problem in their families and the remaining 90.0 % reported no prior occurrence of calculi in their family histories.

Majority (53.3 %) cases were having Chronicity from more than one year, followed by 40.0 % from 6–12 months. Asamsodhanasila , Adhyasana, Apathya Sevana, Tiksnausna Ahara, and Snigdha Ahara were of very dominant type. Ati Avilamutrata , Nabhi Vedana, Mutradhara Sanga and Basti Vedana were the most common problems prevalent in about 80–90 % of the patients. Sevani Vedana was common in 60 % cases. Pain and Burning Micturition were the most dominant complaints (100%) followed by Haematurea (80 %), Dysuria (60 %) and Tenderness (56.7 %). Majority *viz.* 93.3 % of the patients were having stone size : 4 – 8 mm while the remaining 6.3 % patients had stones in the range of : < 4 mm diameter. There were in all 38 calculi sites where this roga was present. Out of these, 63 % were in kidney and 37% in ureter, 79 % were uni-lateral and the remaining 21 % were bi-lateral. There were 79 % stones which occurred singly and 21 % as multiple. The **Kaphaja a**shmari was present in 53 % of the cases, followed by 27 % with **Vataja a**shmari and 20 % with **Pittaja** ashmari conforming to the Prakrti and Nidanas of the patients. Both Ayurvedic & Modern system parameters showed statistical uniformity when evaluated on a 5-point 0-4 graded increasing disease severity scale with respect to K, SP & K+SP groups of patients.

The levels of all the bio-physiological and socio-economic factors present in the K, SP & K+SP group of patients were found to be ***statistically uniform***. But their levels as presented above, certainly indicate their positive role directly or indirectly in the formation and development of Ashmari in the patients. Laboratory investigations done on Hematological, Biochemical and Urological Parameters showed test values in the normal range.

It is, therefore, concluded that the three selected samples of Ashmari patients allocated to K, SP & K+SP, ***were statistically uniform*** and fit for continuing the experimentation further.

Introduction

In India, about 12% of the population is estimated to have urinary stones out of which 50% may end up with loss of kidneys. Also nearly 15% population of North India suffers from such stones. Fewer occurrences of urinary calculi are found in Southern India which may be due to regular dietary intake of Tamarind. Areas of high incidence of urinary calculi include Scandinavian Countries , North Australia, British Isles, Mediterranean countries, Central Europe, Northern India, Pakistan and Saurashtra region. According to an

estimate every year 6 million Americans suffer from urinary stones.

Mutrashmari is a disease pertaining to mutravaha srothas which comes under ***Basti*** marma. Ashmari gets formed when vata dries up the mutra, sukra, pitta or kapha stored in the urinary bladder[1], leading to distention of bladder, severe pain in and around it, difficulty in micturation etc[2] . Formation of Mutrashmari, according to Sushruta, is due to Srotovaiguṇya, resulting from Dusita Kapha localized in Basti, in conjunction with Pradusita Vata and Pitta, is responsible for the cause of Ashmari. Ayurvedic texts have described four types of urinary calculi: sleshmaashmari, pittaashmari, vataashmari, and sukraashmari[3].

A kidney stone is a hardened mass that builds up, gradually when various salts or mineral crystals deposit inside the kidney. These stones are found in all parts of the urinary tract, the kidney, the ureters and the urinary bladder, and urethra, and may vary considerably in size. The most common kind of kidney stone contains calcium combined with either oxalate or phosphate. While in modern medicine, urinary calculi are classified according to their chemical components, for instance uric acid and urates, calcium oxalates, calcium and ammoniomagnesium phosphate (struvite), cystine, combinations of the preceding items.

In Ayurveda the causes of urinary calculi are mainly the non-adoption of purificatory measures such as emesis, purgation, and medicated enemas in order to eliminate the vitiated dosas (toxic materials) and practice of unhealthy diets and lifestyles. These factors are responsible for the formation of calculi[4,5,6]. They are primarily classified into two categories:

a). Unhealthy diet, and b). Excessive physical activity.

In modern medicine, there are three primary factors considered responsible for stone formation: a). The super-saturation of stone-forming compounds in urine, b). The presence of chemical or physical stimuli in urine, and c).Inadequate amount of compounds in urine that inhibit stone formation (e.g., magnesium, citrate).

Diagnosis is usually made on the basis of the location and severity of the pain, which is typically colic in nature. Radiological imaging is used to confirm the diagnosis. Ultrasound imaging is also useful as it will give details about the presence of hydro-nephrosis i.e. suggesting whether the stone is blocking the outflow of urine. It will also show the 10% of stones that do not have enough calcium to be seen on X-rays (radiolucent stones). Besides this, some laboratory tests may be confirmatory.

Different procedures for the management of mutrashmari have been developed in the modern system of medicine but in spite of all these techniques, surgery in some form remains the treatment of choice, yet the recurrence is inevitable in about 60% of cases.

Herbs and herbal drugs have created proven effects like imuno-modulation, adapto-genic and antimuta-genic. Also, the

overuse of synthetic drugs, which result in higher incidence of adverse drug reactions, has motivated humans, to return to nature, for safe remedies. The World Health Organization's Canberre conference in 1976, promoted the concept of 'Traditional' medicines for the developing countries.

A large collection of drugs and mineral compounds efficacious against Ashmari stand already screened and identified in the ancient Ayurvedic texts. The primary work of the present day researcher is to comparatively evaluate the efficacy of these drugs and compounds, and find out their suitability to specific situations so that optimal recommendations could be made. Accordingly, an attempt has been made in this article to present the bench mark level of ***bio-physiological and socio-economic*** parametres of the patients before imposing different treatments on them. The uniformity of the basic raw material namely, the sample patients, drugs etc in respect of these parameters etc, is *sine qua non* for the success of the study.

Materials and Methods

The already screened and identified herbs and drugs in the ancient Ayurvedic texts, are not convincingly acceptable to the modern mind. Further, these classics described signs and symptoms of a disease only subjectively. Thus, it is essential to make the Ayurvedic system:

1. more **scientific** in planning and conduct of experiments ,
2. more **competitive** with other existing systems of medicines in efficacy, etc.
3. more **modern,** urgently needing imbibing of all the latest technological advancements e.g. X-ray, USG etc.

The **first one**, requires conduct of statistically well **planned** trials, the **second one**, is an equally important aspect, because a large number of drugs and mineral compounds are known to cure a particular **ailment** but their relative merits and demerits as well as relative grading in curing etc. in different situations have never been done. While keeping in view the above points, a clinical trial was scientifically planned to evaluate the drugs on mutrashmari disease.

A research experiment was planned to evaluate the comparative efficacy of :

1. **Kulattha Kwath -** a herb known to be effective against Ashmari
2. **Shwet Parpati** – a mineral compound known to be effective against Ashmari
3. **Kulattha Kwath** & **Shwet Parpati** taken in combination

against Ashmari under suburbs of Jammu conditions (JIAR & R.S. Pura, Jammu & Kashmir State). To introduce objectivity into the signs and symptoms of a disease, the concept of **scoring** or **scaling** was adopted, which is extensively used in medical and other socio-economic fields.

Subjective criteria : Assessment of Mutrashmari was done on a increasing symptom severity graded 5-point scale (0 – 4) :

General symptoms score : 0 = Complete absence of signs and symptoms; 1 = Mild degree of signs and symptoms; 2 = Moderate degree of signs and symptoms ; 3 = Severe degree of signs and symptoms; 4 = Acute condition of signs and symptoms

Pain degree score : 0 = No pain ; 1 = Occasional pain, did not require treatment ; 2 = Occasional pain but, required treatment; 3 = Constant dull ache pain, required treatment;

4 = Severe constant pain, but did not show relief even after treatment

Burning micturition degree score : 0 = Burning micturition; 1 = Occasional burning micturition; 2 = Occasional burning micturition, requiring treatment; 3 = Constant burning micturition requiring treatment; 4 = Constant severe burning micturition but no relief even after treatment

Dysuria score : 0 = No dysuria; 1 = Occasional dysuria; 2 = Occasional dysuria requiring treatment; 3 = Constant dysuria which requiring treatment; 4 = Constant severe dysuria but show no relief even after treatment

Tenderness in renal angle score : 0 = No tenderness; 1 = Mild tenderness; 2 = Moderate tenderness; 3 = Severe tenderness; 4 = Acute tenderness

Other classifications: Age: 21–30 years; 31–40 years; 41–50 years; 51–60 years

Religion: Hindu; Muslim; **Gender:** Male ; Female

Socio-economic status: Poor; Lower middle class; Middle class; Upper middle class

Some other attributes were easily understandable in their presence(1) or absence(0). The results were also often presented as frequency, number, percentage etc. for better acceptance in these formats.

Objective criteria : The data generated from laboratory and radiological investigations were statistically analyzed adopting appropriate methods. The different scales adopted for scoring are described below :

Haematuria : 0 = No RBC/Hpf ; 1 = 0–5 RBC/Hpf ; 2 = 6–10 RBC/Hpf ; 3 = 11–15 RBC/Hpf ; 4 = >16 RBC/Hpf.

Pus cells : 0 = No pus cells/Hpf; 1 = 0–5 pus cells/Hpf; 2 = 6 –10 pus cells/Hpf;

3 =1–15 pus cells/Hpf; 4 = >16 pus cells/Hpf.

Similarly, other clinical symptoms were allotted the scores on the basis of severity.

Statistical analysis : Proper statistical analysis of the data generated from the clinical trial was carried out while considering the Completely Randomized Design. Specifically, the following analysis was carried out:

- **Chi-square test** was used ascertain uniformity of the sample cases allocated to K, SP & K+SP groups in respect of the bio-physiological and socio-economic factors

- **Chi-square test** was also used to test the independence of the different bio-physiological & socio-economic factors vis-à-vis the K, SP & K+SP groups
- **Student's t-test** was used for ascertaining the statistical equality of scores relating to the different bio-physiological & socio-economic factors vis-à-vis the K, SP & K+SP groups
- **CD(0.05)** : Critical difference at 5 % level of significance has been worked out to judge the significance of the differences between two mean values. It is in fact a practical form of the **Student's t-test** as mentioned above.

Primary and secondary parametres : Information on a number of parametres was recorded during the course of the Clinical Trial. These parametres were of two types :

- **Primary Parametres** i.e. **directly** linked to the sickness
- **Secondary or Accessory Parametres** i.e. which influence the sickness **indirectly**

Parametres of the **first type** are the **disease symptom parametres** e.g. disease severity, disease rating, disease incidence, disease components, microbiological, bio-chemical, radiological tests etc. The parameters of the **second type** are those which are often predisposing or contributory to disease formation and development. They are : food habits, addiction, socio-economic condition, habitat, age, gender, age etc. They depict and describe the prevailing disease scenario in the population. They are often related to the disease in some manner. They sometimes assist in anticipating or forecasting, preventing the disease in the near future. The collected information after appropriate statistical computations is presented in the tables below.

Note : The tabulated value of **Chi-square** [X^2(degrees of freedom)] is presented in the last cell of the first row, and in the last cell of the first column with degrees of freedom shown in the brackets at 5 % level of significance, while the corresponding calculated chi-square values are in the following rows/columns. The calculated **Chi-square** for the test of independence of the column and row parametres is shown with degrees of freedom in the last cell of the table. However, in some of the tables only Student's t-test or equivalently CD(0.05) values have been provided.

Results & Discussion

Secondary parametres

Age : The age group: 31– 40 years was the major age group covering 43.3 % of patients followed by 26.7 % by age group 21–30 years, and 23.3 % by age group 41–50 years(Table-1). Thus, ***70 % of the Ashmari cases were in the 3rd and 4th decades of life*** i.e. in the age band 21–40 years of age. The K, SP and K+SP groups, statistically did not differ from each other in each age group distribution, and thus represented a similar phenomena. Similarly, the different age groups also did not differ from each other in each of K, SP & K+SP groups. Further, no relationship between the age group and the K, SP, K+SP

classifications of the cases was revealed as a result of non-significant chi-square [tabulated X^2 (6)=12.59 at 5%] test of independence.

Table-1: Age group break-up of the cases.

Group (years)	K	SP	K+SP	Total	%	X^2 (2):5.99
21- 30	4	3	1	8	**26.7**	2.39
31- 40	4	4	5	13	**43.3**	0.27
41- 50	2	3	2	7	**23.3**	0.37
51- 60	0	0	2	2	**6.7**	4.29
Total	10	10	10	30	**100.0**	-
X^2 (3):7.82	4.40	3.60	3.60	-	-	**X^2 (6)** 6.19

Gender : Males outnumbered females in the sample patients(Table-2). The sample comprised 63.3 % males and 36.7 % females. On overall basis, *the* ***Female : Male ratio*** *worked out to* ***1.00 : 1.72*** *i.e.* ***about 1: 2 ratio.*** Statistically, similar gender pattern prevailed in K, SP and K+SP groups. Non-significant contingency chi-square showed independent allocation of the gender cases to K, SP & K+SP groups.

Table-2: Gender break-up of the cases.

Gender	K	SP	K+SP	Total	%	X^2(2):5.99
Female	3	4	4	11	**36.7**	0.29
Male	7	6	6	19	**63.3**	0.29
X^2(1):3.84	1.60	0.40	0.40	-	**36.7**	**X^2(2):5.99** 0.29

Religion : The sample cases were affiliated to only two religions viz. Hindu and Muslim (Table-3). On overall basis, there were 83.3 % Hindus and 16.7 % Muslims. Statistically, similar pattern is discernible from K, SP and K+SP groups. Widely different representations of the two religions in the sample does not reflect any relationship with the disease, but they merely indicate the ***actual relative presence of these two communities in the study area***

Table-3: Religious affiliations of the cases.

Religion	K	SP	K+SP	Total	%	X^2(2):5.99
Hindu	8	8	9	25	**83.3**	0.48

Muslim	2	2	1	5	**16.7**	0.48
X^2 (1):3.84	3.60	3.60	6.40		-	**X^2(2):5.99** 0.48

Table-4: Habitat of the cases.

Habitat	**K**	**SP**	**K+SP**	**Total**	**%**	**X^2(2):5.99**
Rural	7	8	7	22	**73.3**	0.34
Urban	3	2	3	8	**26.7**	0.34
X^2 (1):3.84	1.60	3.60	1.60	-	-	**X^2(2):5.99** 0.34

Table-5: Occupation pursuit of the cases.

Occupation	**K**	**SP**	**K+SP**	**Total**	**%**	**X^2(2):5.99**
Farmer	5	4	4	13	**43.4**	0.27
House wife	3	2	2	7	**23.3**	0.37
Labourer	2	2	3	7	**23.3**	0.37
Student	0	2	1	3	**10.0**	2.22
X^2 (3):7.82	5.20	1.20	2.00	-	-	**X^2(6):12.59** 2.73

Habitat : Patients from both rural and urban localities were represented in the sample (Table-4). On overall basis, ***73.3 % of the cases hailed from rural areas and the rest 26.7 % from urban areas***. Statistically, a similar pattern is noticeable in K, SP and K+SP groups of patients.

Occupation : Occupationally, 66.7 % of the Ashmari cases belonged to the working class namely, farming (43.4%) and labour (23.3%), both having a higher likelihood of forming calculi(Table-5). The sample adequately covered the lower socio-economic classes (63.0%), known to be prone to Ashmari formation. The sample comprised farmers, labourers, housewives and students. On overall basis, ***farmers were the major category (43.4 %) followed by housewives (23.3 %) and labourers (23.3 %)***. Students constituted only 10.0 % of the cases. Statistically, a similar pattern prevailed in each of the K, SP and K+SP groups.

Table-6: Educational Status of the cases.

Education	**K**	**SP**	**K+SP**	**Total**	**%**	**X^2(2):5.99**
PG	1	0	1	2	6.6	1.071
Graduate	1	4	0	5	16.7	6.240
Higher Sec.	5	3	6	14	46.7	1.875
Primary	2	1	3	6	20.0	1.250
Illiterate	1	2	0	3	10.0	2.222
X^2 (4):9.49	6.000	5.000	13.000	-	-	**X^2(8):15.51** 10.200

Education : Almost the whole spectrum of education was represented in the sample (Table-6). On **overall basis**, 70 % cases were either Higher Sec. pass are above. ***Higher secondary 46.7 % was the major category*** followed by Primary (20.0 %) and Illiterate (10.0 %) . Statistically, the same trend was present in K, SP and K+SP groups.

Marital status : On **overall basis**, *80.0 % of the patients were married and only 20 % were unmarried*(Table-7). Exactly same pattern was present in K, SP and K+SP groups. The results are presented.

Table-7: Marital status of the cases.

Status	K	SP	K+SP	Total	%	$X^2(2):5.99$
Married	8	8	8	24	**80.0**	0.00
Unmarried	2	2	2	6	**20.0**	0.00
$X^2(1):3.84$	3.60	3.60	3.60	-	-	**$X^2(2):5.99$** 0.00

Socio-economic status : On **overall basis**, Lower middle class comprised 50 %, Middle class comprised 30.0 % of the cases while the representation of Upper middle class and Poor class was relatively insignificant(Table-8). Statistically, the same trend was noticed in K, SP and K+SP groups . Thus, ***the sample adequately covered the lower socio-economic class (63.3%) more prone to the disease***.

Table-8: Socio-economic status of the cases.

Class	K	SP	K+SP	Total	%	$X^2(2):5.99$
Upper middle	0	1	1	2	**6.7**	1.07
Middle	2	4	3	9	**30.0**	0.95
Lower middle	5	4	6	15	**50.0**	0.80
Poor	3	1	0	4	**13.3**	4.04
X (3):7.82	5.20	3.60	8.40	-	-	**$X^2(6):12.59$** 5.57

Body constitution : Four types of body constitutions viz. Asthenic, Normoasthenic, Pthisical and Sthenic were represented in the sample (Table-9). On **overall basis**, there were 36.7 % cases each in Asthenic and Normoasthenic categories, while 16.6 % and 10. 0 % belonged to Sthenic and Pthisical categories respectively. Statistically, similar pattern is noticeable in K, SP and K+SP groups. It may be mentioned that ***the patients belonging to pthisical and other sicknesses were in the first stage*** i.e. curable and were on treatment.

Table-9: Body constitution of the cases.

Constitution	K	SP	K+SP	Total	%	$X^2(2):5.99$
Asthenic	3	4	4	11	**36.7**	0.29
Normoasthenic	4	3	4	11	**36.7**	0.29
Pthisical	1	2	0	3	**10.0**	2.22
Sthenic	2	1	2	5	**16.6**	0.48
$X^2(3):7.82$	2.00	2.00	4.40	-	-	**$X^2(6):12.59$** 2.76

Addiction : The prevalence of addiction to tea, coffee, alcohol, tobacco chewing and smoking was assessed in the sample cases (Table-10). On **overall basis**, *addiction to tea (100 %), tobacco chewing and smoking (70 % each) and alcohol (66.7 %) indicate excessive intake of harmful intoxicants likely to support Ashmari development*. Only addiction to coffee was insignificant. Statistically, similar addiction prevalence was present in K, SP and K+SP groups.

Table-10: Prevalence of addiction in the cases.

Addiction	K	SP	K+SP	Total	%	$X^2(2):5.99$
Tea	10	10	10	30	**100.0**	**0.00**
Coffee	0	1	1	2	**6.7**	**1.07**
Alcohol	7	6	7	20	**66.7**	**0.30**
Tobacco	6	8	7	21	**70.0**	**0.95**
Smoking	7	7	7	21	**70.0**	**0.00**
Total	10	10	10	30	**100.0**	-

Sleep Behaviour: On **overall basis** , *50 % cases reported disturbed sleep while 46.7 % reported normal sleep* (Table-11). Only 3.3 % cases had occasionally disturbed sleep. Statistically, similar behaviour was observed in K, SP and K+SP groups.

Table-11: Sleep behaviour of the cases.

Sleep	K	SP	K+SP	Total	%	$X^2(2):5.99$
Disturbed	4	6	5	15	**50.0**	0.80
Normal	5	4	5	14	**46.7**	0.27
Disturbed Occasionally	1	0	0	1	**3.3**	2.07
$X^2(2):5.99$	2.6	5.6	5.0	-	-	**$X^2(4):9.49$** 2.54

Diet : Two types of diets namely, vegetarian and mixed (vegetarian as well as non-vegetarian) foods were considered in this study (Table-12). On **overall basis**, the cases belonging to both these diets were equally represented in the Sample. *Fifty percent of the sample cases*

consumed mixed diet i.e. the diet rich in fats, sodium, calcium etc which increases the chances of calcium salt crystallization, leading to Ashmari formation. Statistically, the same behaviour is noticeable in K, SP and K+SP groups.

Table-12: Diet types of the cases.

Diet	K	SP	K+SP	Total	%	$X^2(2):5.99$
Mixed	6	5	4	15	**50.0**	0.80
Vegetarian	4	5	6	15	**50.0**	0.80
$X^2(1):3.84$	0.40	0.00	0.40	-	-	**$X^2(2):5.99$** 0.80

Dietetic habits : Response to four types of Dietetic habits namely, Adhyasana, Anamasana, Samasana and Visamasana was recorded from the cases (Table-13). On **overall basis**, *majority (46.7 %) of the cases were having Adhyasana followed by 23.3 % having Visamasana thus helping in ama formation, the latter vitiates the dosas and localizing at mutravaha srotasas causing srotorodha and leading to Ashmari formation.* Statistically, similar pattern was observed in K, SP and K+SP groups.

Table-13: Dietetic Habits of the cases.

Dietetic Habits	K	SP	K+SP	Total	%	$X^2(2):5.99$
Adhyasana	4	5	5	14	**46.7**	0.28
Anamasana	1	1	1	3	**10.0**	0.00
Samasana	2	2	2	6	**20.0**	0.00
Visamasana	3	2	2	7	**23.3**	0.37
$X^2(3):7.82$	2.00	3.60	3.60	-	-	**$X^2(6):12.59$** 0.43

Dominant rasa : Prevalence of all the four rasas namely, Madhura, Amla, Lavana, Katu, Tikta and Kasaya was recorded on the sample patients (Table-14). On **overall basis**, *Madhura rasa was the most dominant (90.0 %.), followed by Katu (50.0 %) known to be more prone to disease Ashmari.* Tikta (50.0 %.), and Amla & Lavana rasas were involved in about 20 % of the patients. Statistically, the same trend was observed in K, SP and K+SP groups.

Table-14: Dominant rasa types in the cases.

Rasa Type	K	SP	K+SP	Total	%	$X^2(2):5.99$
Madhura	10	8	9	27	**90.0**	0.18
Amla	2	2	3	7	**23.3**	0.19
Lavana	3	1	2	6	**20.0**	0.87
Katus	5	4	6	15	**50.0**	0.175

Tikta	3	5	4	12	**40.0**	1.08
Kasaya	0	0	0	0	-	0.00

Agni bala : The relative distribution of Sama , Visama, Tiksna and Manda Agni Balas was studied in the sample patients. The results are presented in Table–15. On **overall basis**, *Manda and Sama Agni Bala were the most predominant (30 % each) rasa types which are known to play a role in Ashmarii formation.* Tiksna and Visama Agni Bala were present in about 16 – 20 % of the patients. The cases in K, SP and K+SP groups followed a similar pattern statistically.

Table-15: Agni bala types of the cases.

Agni Bala	K	SP	K+SP	Total	%	$X^2(2):5.99$
Sama	4	3	2	9	**30.0**	0.95
Visama	2	2	1	5	**16.7**	0.48
Tiksna	1	2	3	6	**20.0**	1.25
Manda	3	3	4	10	**33.3**	0.30
$X^2(3):7.82$	2.000	0.40	2.00	-	-	**$X^2(6):12.59$** 2.27

Table-16: Sarira Prakriti of the cases.

Prakriti	K	SP	K+SP	Total	%	$X^2(2):5.99$
Kapha-Pitta	3	3	1	7	**23.3**	1.49
Vata-Kapha	5	5	4	14	**46.7**	0.27
Vata-Pitta	2	2	5	9	**30.0**	2.86
$X^2$2):5.99	1.40	1.40	2.61	-	-	**$X^2(4):9.49$** 3.29

Sharira prakriti : Information on three types of prakriti namely, Kapha-Pitta, Vata-Kapha and Vata-Pitta was also recorded (Table-16). On **overall basis**, about 46.7 % cases were having Vata-Kaphaja Prakrti, followed by 30 % of Vata-Pitta Prakriti and 23.3 % of Kapha-Pitta Prakriti favouring the formation of Ashmari. Statistically, a similar trend was observed in K, SP and K+SP groups of patients.

Kostha: Information on three Kostha types namely, Mridu, Madhyama and Krra was also collected(Table-17). On **overall basis**, *Madhyama Kostha was the most predominant type (76.7 %), followed by Mridu (23.3 %).* No response to Krra Kostha was found. The results were statistically,consistent over the K, SP and K+SP groups.

Table-17: Kostha types in the cases.

Kostha	K	SP	K+SP	Total	%	$X^2(2):5.99$
Mridu	2	3	2	7	**23.3**	0.37
Madhyama	8	7	8	23	**76.7**	0.37
Krra	0	0	0	0	**0.0**	0.00
$X^2(1): 3.84$	3.6	1.6	3.6	-	-	**$X^2(2):5.99$** 0.37

Ahara shakti : Information on three types of Ahara Shakti viz. Avara, Madhyama and Pravara was assessed from the patients. The results are presented in Table-18. On **overall basis**, patients were almost equally distributed into these three types of Ahara Prakriti. Statistically, same pattern was noticed in K, SP and K+SP groups.

Table-18: Ahara Shakti of the cases.

Ahara Shakti	K	SP	K+SP	Total	%	$X^2(2):5.99$
Avara	4	2	3	9	**30.0**	0.95
Madhyama	3	4	4	11	**36.7**	0.30
Pravara	3	4	3	10	**33.3**	0.30
$X^2(2):5.99$	0.20	0.80	0.20	-	-	**$X^2(4):9.49$** 1.05

Vyama shakti : Vyama shakti was also assessed in three categories namely, Avara, Madhyama and Pravara(Table-19). On **overall basis**, about 47 % of the cases fell in Avara category, 43.3 % in Madhyama category, while only 10.0 % belonged to Pravara category. Higher percentage was recorded in Avara category in K group, and in Madhyama category in K+SP group, while Pravara category maintained consistently low percentage (10.0 %) in the three groups. The K, SP & K+SP groups did not differ from each other statistically

Table-19: Vyama-Shakti of the cases.

Vyama-shakti	K	SP	K+SP	Total	%	$X^2(2):5.99$
Avara	5	5	4	14	**46.7**	0.27
Madhyama	4	4	5	13	**43.3**	0.27
Pravara	1	1	1	3	**10.0**	0.00
$X^2(2):5.99$	2.60	2.60	2.60	-	-	**$X^2(2):5.99$** 1.01

Family calculi history : On **overall basis**, *only 10.0 % patients reported calculi problem in their families and the remaining 90.0 % reported no prior occurrence of calculi in their family histories*(Table-20). Statistically, similar results were recorded in K, SP and K+SP groups.

Chronicity of ashmari : The chronicity of Ashmari was recorded for three durations, namely less than 6 months, 6 – 12 months and greater than 12 months(Table-21). On **overall basis**, *about 53 % patients were having the calculi problem older than 12 months, 40.0 % had it from the last 6 – 12 months*, while 6.7 % of the patients were having the problem only recently. Statistically, similar pattern was observed in K, SP and K+SP groups.

Table-20: Family history of calculi in the cases.

Calculi	K	SP	K+SP	Total	%	$X^2(2):5.99$
Absent	9	10	8	27	**90.0**	2.22

Present	1	0	2	3	**10.0**	2.22
X^2(1):3.84	6.40	10.00	3.60	1.92	-	**X^2(2):5.99** 2.22

Table-21 : Calculi chronicity in months of the cases.

Chronicity (months)	K	SP	K+SP	Total	%	X^2(2):5.99
< 6 months	1	0	1	2	**6.7**	1.07
6 – 12 months	4	5	3	12	**40.0**	0.83
> 12 months	5	5	6	16	**53.3**	0.27
X^2(2):5.99	2.60	5.00	3.80	-	-	**X^2(4):9.49** 1.63

Nidana sevana : A number of Nidana Sevana types were considered for assessing their prevalence in the sample patients (Table-22). On **overall basis**, *Asamsodhanasla was the most dominant type with a prevalence of 93.3 %, Adhyasana, Apathya Sevana, Tiksnausna Ahara, and Snigdha Ahara were also of very dominant type prevalent in around 70–80 % of the patients and are, therefore, the predisposing factors for Ashmari formation.* Mamsa Sevana and Ajirna Sevana types were common among about 50–60 % of the patients, while Sita Ahara and Guru Ahara were common, each in 50 % of the cases. Matsya Sevana, Samasana and Ativyama types were prevailent in 20–30 % cases. The remaining types had little place in the Nidana Sevana of the sample cases. The groups K, SP and K+SP behaved in a similar manner statistically.

Table-22: Nidana sevana of the cases.

Nidana Sevana	K	SP	K+SP	Total	%	X^2(2):5.99
Asamsodhanasla	10	10	8	28	**93.3**	4.29
Apathya Sevana	8	7	8	23	**76.7**	0.37
Divaswapa	7	6	5	18	**60.0**	0.83
Samasana	2	3	2	7	**23.3**	0.37
Adhyasana	7	9	8	24	**80.0**	1.25
Sita Ahara	6	4	5	15	**50.0**	0.80
Snigdha Ahara	6	7	8	21	**70.0**	0.95
Guru Ahara	4	6	5	15	**50.0**	0.80
Madhura Ahara	5	6	7	18	**60.0**	0.83
Tiksnausna Ahara	7	8	6	21	**70.0**	0.95
Madhya Sevana	0	0	0	0	**0.0**	0.00
Matsya Sevana	4	2	3	9	**30.0**	0.95
Ajirna Sevana	6	5	6	17	**56.7**	0.27
Mamsa Sevana	7	4	6	17	**56.7**	1.90
Ativyama	3	4	3	10	**33.3**	0.30
Mutra Avrodhana	0	0	0	0	**0.0**	0.00
Pitruja Dosa	1	0	1	2	**6.7**	1.07
Matruja Dosa	0	1	0	1	**3.3**	2.07

Primary parametres

Major complaints:

A. Ayurvedic system : Information on a number of major Ayurvedic complaints was recorded. The results are presented in Table–23. **On overall basis**, *Ati Avilamutrata, Nabhi Vedana, Mutradhara Sanga and Basti Vedana were the most common problems prevalent in about 80–90 % of the patients. Sevani Vedana was common in 60 % cases.* Sarudhira Mutrata, Mehan Vedana and Gomeda Prakasam were present in about 35-45 % of the patients. Mutra Vikirana, Sasikitam, Visirnadhara, and Mrudanti Medhara were present in about 10 % of the cases were relatively insignificant in importance. Statistically, the same trend was noticed in K, SP and K+SP groups.

Table-23:Major Ayurvedic complaints of the cases.

Complaint	K	SP	K+SP	Total	%	$X^2(2):5.99$
Nabhi Vedana	8	8	10	26	**86.7**	2.32
Basti Vedana	9	7	8	24	**80.0**	1.25
Sevani Vedana	4	8	6	18	**60.0**	3.33
Mehan Vedana	3	5	5	13	**43.3**	1.09
Mutradhara Sanga	7	9	8	24	**80.0**	1.25
Sarudhira Mutrata	3	5	3	11	**36.7**	1.15
Mutra Vikirana	2	1	0	3	**10.0**	2.20
Ati Avilamutrata	7	8	10	25	**83.3**	3.36
Sasikitam	2	1	0	3	**10.0**	2.22
Visirnadhara	2	1	0	3	**10.0**	2.22
Mrudanti Medhara	2	1	0	3	**10.0**	2.22
Gomeda Prakasam	4	5	4	13	**43.3**	0.27

Table-24: Major Modern system complaints of the cases.

Complaint	K	SP	K+SP	Total	%	$X^2(2):5.99$
Pain	10	10	10	30	**100.0**	0.00
Burning Micturition	10	10	10	30	**100.0**	0.00
Haematuria	10	4	4	18	**60.0**	10.00**
Dysuria	7	8	9	24	**80.0**	1.25
Nausea & Vomiting	0	0	0	0	**0.0**	0.00
Fever	0	0	0	0	**0.0**	0.00
Tenderness	5	6	6	17	**56.7**	0.27

** : P<0.01

B. Modern system : The patients' impressions were also sought on seven major problems, generally faced by the urolithiasis patients. These were : Pain, Burning Micturition Burning Micturition, Dysuria, Nausea & Vomiting, Fever and Tenderness. The results are presented in Table–24. **On overall basis**, *Pain Burning Micturition were the most dominant problems afflicting all the cases followed by Haematurea (80 %), Dysuria (60 %) and Tenderness (56.7 %).* Nausea & Vomiting and Fever were not at all important problems of the sample patients. Statistically, similar pattern prevailed in K, SP and K+SP groups excepting Haematurea . K group had significantly higher incidence of Haematurea in comparison to SP & K+SP groups.

Sites of calculi: Mutrashmari roga was primarily located in kidney and ureter organs of the sample patients. None of the registered (OPD) bladder stone patients met the inclusion criteria, particularly pertaining to the size of the calculi, so none of them could be inducted into the Clinical Trial(Table-25a). On **overall basis**, *there were in all 38 mutrashmari sites where this roga was present. Out of these, 63 % were in kidney and 37 % in ureter.* There were 12 sites of Ashmari in K, 14 in SP and 12 in K+SP groups.

Table-25a : Number and Site of stones in the cases.

Site	K*					SP					K+SP					Total					$X^2(2):5.99$
	S	M	B	T	%	S	M	B	T	%	S	M	B	T	%	S	M	B	T	%	
Kidney	5	1	1	**9**	**75**	4	1	1	**8**	**57**	5	1	0	**7**	**58**	14	3	2	**24**	**63**	**1.061**
Ureter	3	0	0	**3**	**25**	2	1	1	**6**	**43**	3	0	1	**5**	**42**	8	1	2	**14**	**37**	**1.061**
$X^2(1):3.84$	**1.057**					**0.345**					**0.175**					-					**$X^2(2):5.99$ 1.061**

*: S=Single & Unilateral, M=Multiple(double) & Unilateral, B=Bilateral & Single, T=Total

Uni-lateral and bi-lateral stones : There were in all 38 ashmari sites, *out of which 30 (79 %) were uni-lateral and the remaining 8 (21 %) were bi-lateral* (Tab le-25b). K group had 12 stone sites, out of which 10 (83%) were uni-lateral and 2 (17 %) bi-lateral. SP group had 14 sites, 10 (71 %)were uni-lateral and 4 (29%) were bi-lateral. While there were 12 ashmari sites in K+SP group, out of which 10 (83 %) were uni-lateral and 4 (17 %) were bi-lateral.

Table–25 b: Uni/Bi-lateral stones in the cases.

Stone	K	SP	K+SP	Total	%	$X^2(2):5.99$
Unilateral	10	10	10	30	**79**	0.754
Bilateral	2	4	2	8	**21**	1.815
$X^2(1):3.84$	0.203	0.754	0.378	-	-	**$X^2(2):5.99$** 0.754

Table–25 c: Single/Multiple stones in the cases.

Site	K	SP	K+SP	Total	%	$X^2(2):5.99$
Single	10	10	10	30	**79**	0.754
Multiple	2	4	2	8	**21**	1.815
$X^2(1):3.84$	0.203	0.754	0.378	-	-	**$X^2(2):5.99$** 0.754

Single and multiple stones : Single and multiple stones followed the pattern of the Unilateral an Bilateral (Table-25c).

Size range of calculi : Calculi were classified into two size ranges namely < 4 mm & 4 – 8 mm. Further, if a patient was having calculi at more than one site, he was included in the study(Table–26) for his largest calculi size only. On **overall basis**, *most of the calculi cases i.e. 93.7 % were in the size range of 4 – 8 mm and the remaining 6.7 % cases were in the range of < 4 mm.* The K, SP & K+SP groups did not differ statistically in respect of the number of calculi sizes allocated to them.

Table–26: Calculi sizes in the cases.

Size(mm)	K	SP	K+SP	Total	%	$X^2(2):5.99$
< 4 mm	1	0	1	2	**6.7**	1.07
4 – 8 mm	9	10	9	28	**93.3**	1.07
$X^2(1):3.84$	6.40	10.00	6.40	-	-	**$X^2(2):5.99$** 1.07

Ashmari types

All the three types of Ashmari viz. Kaphaja, Pittaja and Vataja were found in the patients. The results are reported in Table–27a. **On overall basis**, ***Kaphaja*** *Ashmari represented 53 % of the cases, followed by 27 % in* ***Vataja*** *Ashmari and 20 % in* ***Pittaja*** *Ashmari conforming to the Prakrti and Nidanas of the patients.* This shows the dominance of Kaphaja type of Ashmari in the study area. Statistically, similar pattern of Ashmari types was found in K, SP and K+SP groups, also the chi-square test of independence of the factor-1 : Ashmari types and the factor-2 : K, SP, K+SK groups was non-significant i.e. indicating independence of these two factors.

Table-27a: Ashmari Types present in the cases.

Type	K	SP	K+SP	Total	%	$X^2(2):5.99$
Kaphaja	6	5	5	16	**53**	0.268
Pittaja	1	2	3	6	**20.0**	3.065
Vataja	3	3	2	8	**27**	0.341
$X^2(2):5.99$	0.938	0.094	1.410	-	-	**$X^2(4)$:9.49** 1.375

Location of the Calculi in the different Ashmari Types. Kidney was the major calculi site in Kaphaja Ashmari cases while Kidney and Ureter were nearly equally present in Pittaj and Vataj Ashmari types in the area (Table-27b). Statistically significant differences were observed among the K, SP & K+SP groups in the case of Vataja patients only. Significant differences were also observed among the Ureter cases in K+SP group of the patients.

Table-27b : Calculi Sites in Different Ashmari Types.

Ashmari Type	Site	K				SP				K+SP				Total				$X^2(2):5.99$
		S	M	B	T	S	M	B	T	S	M	B	T	S	M	B	T	
Kaphaja	**Kidney**	2	1	1	**6**	3	1	0	**5**	3	1	0	**5**	8	3	1	**16**	0.134
	Ureter	2	0	0	**2**	0	0	1	**2**	1	0	0	**1**	3	0	1	**5**	1.804
Pittaja	**Kidney**	1	0	0	**1**	0	0	0	**0**	2	0	0	**2**	3	0	0	**3**	2.812
	Ureter	0	0	0	**0**	1	1	0	**3**	1	0	0	**1**	2	1	0	**4**	2.730
Vataja	**Kidney**	2	0	0	**2**	1	0	1	**3**	0	0	0	**0**	3	0	1	**5**	3.541
	Ureter	1	0	0	**1**	1	0	0	**1**	1	0	1	**3**	3	0	1	**5**	5.781
$X^2(2):5.99$	**Kidney**	0.036				3.131				5.544								$X^2(4):9.49$ 5.038
	Ureter	2.121				2.771				7.566				-				4.550

*: S= Single & Unilateral, M=Multiple(double) & Unilateral, B=Bilateral & Single, T=Total

To more realistically, evaluate the level of Ashmari disease present in the sample cases, their responses were assessed on an increasing symptom severity 5-point 0-4 graded disease scores in respect of both the Ayurvedic and modern system parameters as follows:

Table-28: Mean scores of Ayurvedic parametres.

Parametre	K	SP	K+SP	Mean	CD(0.05)
Nabhi Vedana	2.3*	2.4	2.3	2.3	1.2
Basti Vedana	1.7	1.2	1.3	1.4	0.9
Sevani Vedana	1.1	1.2	1.1	1.1	1.1
Mehan Vedana	0.5	0.9	0.9	0.8	0.9
Mutra Sanga	1.2	1.9	2.2	1.8	1.1
Sarudhiramutrata	0.7	0.7	0.6	0.7	0.9
Gomeda Prakasam	0.7	0.9	0.8	0.8	0.4

Atiavila Mutrata	1.7	1.8	2.2	1.9	1.0

*: each based on 10 cases.

Ayurvedic parameters : Since, no significant level of Mutra Vikirana, Sasikitam, Visirnadhara, and Mrudanti Medhara described in the preliminary investigations(Table-23), therefore, they were not considered in the subsequent study. All the remaining parameters (Table-28) show statistical uniformity in the Ashmari disease levels in K, SP and K+SP groups of cases.

Modren system parameters : All the parameters (Table-29) showed statistical uniformity in the Ashmari disease levels in K, SP and K+SP groups of cases. Nausea & Vomiting, and Fever parametres did not show any affect in the preliminary investigations (Table-24), therefore, they were excluded in the subsequent analysis.

Table-29: Mean scores of modern system parameters.

Parametre	K	SP	K+SP	Mean	CD(0.05)
Pain	3.1*	2.7	3.4	3.1	0.7
Burning Micturition	1.9	1.8	2.1	1.9	0.5
Haematuria	1.8	1.0	1.1	1.3	1.2
Dysuria	1.3	1.7	1.9	1.6	1.0
Tenderness in renal angle	0.8	1.0	1.1	1.0	0.9

*: each based on 10 cases

Laboratory investigations

Laboratory investigation results were statistically analysed to ascertain the deviations of samples of cases allocated to K, SP & K+SP groups. The results for Hematological, Bio-chemical and Urological Parameters are presented in the Table–36.

All the parametres, were within their **normal limits**. The K, SP and K+SP groups of cases showed statistical uniformity in all the laboratory tests conducted on the cases.

Laboratory Investigations : The results for Hematological Bio-chemical and Urological Parameters are presented in the Table – 36. Pre-therapy laboratory investigation results were statistically analyzed. The CD(0.05) values show that the K, SP & K+SP groups did not differ from each other in respect of these parameters.

Table–30: Laboratory Tests of the cases.

Parametres	K	SP	K+SP	CD(0.05)	Parametres	K	SP	K+SP	CD(0.05)
Neutrophils*	56.7	57.9	58.8	7.2	**S. chloride**	102	101	102	3

Lymphocytes*	34.4	30.8	33.3	3.9	**S. calcium**	9.2	9.4	9.5	0.4
Eosinophils*	4.1	4.2	3.9	0.5	**S. phosphate**	3.7	3.4	3.5	0.4
Monocytes*	6.0	6.9	6.3	1.5	**S. albumin**	4.2	4.2	4.2	0.4
TLC*	8390	8640	8010	589	**S. globulin**	2.7	2.3	2.5	0.3
ESR	14.8	16.5	19.8	3.8	**S. uric acid**	4.3	4.2	4.7	0.7
Hb gm%	10.3	9.9	10.3	0.6	**F. Blood Sugar**	80.1	82.5	88.4	8.1
Blood Urea L	29.7	27.6	30.0	3.9	**pH**	4.7	5.4	5.3	0.4
S. creatinine	0.94	0.94	0.95	0.19	**RBC***	1.4	1.9	1.9	1.3
S. cholesterol	195	190	198	18	**Pus Cells***	0.9	1	0.8	0.7

*: Count.

Conclusion : Thus, from the discussion of the results presented above, it may be safely concluded that the sample cases which were allocated randomly to the three study groups namely, K: Kuluttha, SP: Shwet Parpati, & K+SP were statistically uniform in all the bio-physiological parameters, and it is worth to initiate the treatments on the subjects as planned.

From the above presentation it is pretty clear that the three selected samples of Ashmari patients allocated to K, SP & K+SP, are statistically very uniform for imposing these clinical treatments on them for assessing their comparative efficacy in the management of Mutrashmari.

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