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A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFICACY OF AVAPEEDAKA SNEHAPANA IN FIXED AND INCREASING DOSE WITH TRINAPANCHAMOOLA GHRITA IN MOOTRASHMARI (UROLITHIASIS)

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ABSTRACT

Mutrashmari is one of the most common conditions of *Mutravahasrotas* in which stone is formed in urinary tract. The word *Ashmari* in *Sanskrit* denotes the stone or calculi and *Mutra* means urine. *Mutrashmari* is a dreadful condition and has potential to disturb the anatomy and physiology of the urinary system. Once it is formed in the body it tends to have recurrence thus get difficult to cure. Hence it is included under *Ashtamahagada*. In modern medical system it is correlated with urinary calculi or Urolithiasis based on their signs and symptoms. Factors such as diet, water, climate, geographical conditions are also play a major role in causing *Mutrashmari*.

Ayurveda basically aims at prevention of formation of *Mutrahmari* along with expulsion of existing calculi. In *Ayurveda* texts administration of oral medication in different forms such as *Ghrita*, *Kshara*, *Kashaya* and other *Shamanousadhi*, *Shodhana Karma* and *Shastra Karma* are emphasized for management of *Mutrashmari*. *Snehapana* is the basic principle in the management which is to be adopted in primary stage of *Mutrashmari*. In the present study *Trinapanchamoola Ghrita* having properties such as *Ashmaribhedana*, *Ashmari Patana* and *Mutrala* activities has been taken up as indicated in *Vangasena* for *Ashmari*.

KEY WORDS: *Mutrashmari*, *Snehana*, *Avapeedaka Snehapana*, urolithiasis.

INTRODUCTION

Purusha is made up of *Sneha Sara*(essence). *Sneha* is responsible for holding *Prana*(life). Hence, *Snehana* plays major role in treating majority of the diseases. Among all the varieties of *Snehanapana*, *Avapeedaka Snehapana* is a special type of *Snehapana* which is administered in *Yojana Dwaya* pattern in *Uttama Matra*[1]. *Avapeedaka Snehapana* is a procedure in which *Sneha* is consumed before food and after digestion of food. This treatment modality is specially indicated in *Adhonabhigata Vikaras, Mootravega avarodhajanya Vikaras*[2].

Mutrashmari is one of the most common disorders of *Mutravaha Srotas,* having *Lakshanas* like *Mahati Vedana, Sarudhira Mutrata, Vedana* in *Nabhi, Basti Pradesha, Mootradhara Sanga*, *Mutradaha* and *Mutrakrichra*[3]. In contemporary medicine, *Mutrashmari* can be corelated with Urolithiasis. Treatment modalities are flush therapy when stone is up to 5mm size; in larger stones-surgery[4]. However, it is better to opt for medical management before going for surgical intervention. *Snehapana* is considered as the first line of management in *Mutrashmari*[5]. Hence *Avapeedaka Snehapana* in fixed and in increasing dose with *Trinapanchamooladi Ghrita*[6] was opted in the present study.

MATERIALS AND METHODS

SOURCE OF DATA

Subjects were selected randomly from the OPD and IPD of Government *Ayurveda* College and Hospital, Mysore and Hitech Panchakarma Hospital, Mysore who fulfilled the inclusion criteria of the study irrespective of their sex, religion etc.

SOURCE OF THE DRUG

Formulation *Trinapanchamooladi Ghrita* mentioned in *Vangasena*, manufactured by S.N. Pandit and son's Co. Pvt. Ltd, Mysuru, (a GMP certified pharmacy) was procured for the purpose of study.

DIAGNOSTIC CRITERIA

Diagnosis was made on the basis of ultrasonography and CT of Kidney, Ureter, Bladder (KUB) and signs and symptoms of *Mutrashmari* -*Shula*(pain) in *Nabhi* and *Basti Pradesha*, *Mutradaha* (burning micturition), *Mutrakruchra* (dysuria), *Sarudhira Mutrata* (urine mixed with blood).

INCLUSIVE CRITERIA

1.Subjects who fulfilled the diagnostic criteria.
2.Subjects of 18-50 years of age group irrespective of gender, caste, religion were included.
3.Subjects with or without clinical features of *Mutrashmari* diagnosed with presence of urinary calculi (solitary or multiple) by radiological investigation measuring up to 5mm anywhere in (KUB) kidney, ureter, and bladder were included in the study.

EXCLUSIVE CRITERIA

1.Subjects unfit for *Snehapana*.
2.Subjects having obstructive urolithiasis, urethral stricture, CA ureter, Renal failure, Severe hydronephrosis, acute urinary tract infection, retention of urine due to any other Pathology.
3.Subjects with other systemic illness which interfere with intervention.
4.Pregnant and lactating women.

STUDY DESIGN

A comparative Clinical study with pre and post-test design.

PLAN OF STUDY

A. Sample size & Grouping:

40 subjects were randomly divided into 2 groups, A & B with 20 subjects in each group. For Group A *Avapeedaka Snehapana* was given in fixed dose and for group B it was in increasing dose.

B. Sampling method

Purposive sampling method was followed.

Study duration

The study duration was 15 days

INTERVENTION-

AVAPEEDAKA SNEHAPANA

***PURVAKARMA*:**

Deepana Pachana - *Chitrakadi Vati* 250mg before food three times a day with *Sukhoshna Jala* till attainment of *Nirama Lakshanas*.
Dose assessment -

- *Snehapana* was started with *Hrisiyasi Matra* of 30ml for both groups to know the *Agni* and *Koshta*.
- Time taken for digestion of *Hrisiyasi Matra* was noted.
- On the basis of the above data, *Uttama Matra Sneha* was calculated

***PRADHANA KARMA*:**

- On the next morning, in *Kshudhita Avastha* and *Ananna Kala*, after ascertaining the *Jeernahara Lakshanas Sneha* was administered.
- The calculated *Uttama Matra* of *Trinapanchamoola Gritha* was divided in to two doses. 1/4th dose (*Hrisva Matra)* was given as *Pragbhakta Sneha.* After attaining *Sneha Jeerna Lakshana*, *Laghu Bhojana* (ganji, khichadi) was given. After the digestion of this food, the remaining dose, i.e 3/4th (*Uttama Matra)* was given as *Ahara Jeernantika Sneha*
- *Anupana- Ushna Jalapana* was advised throughout the procedure.

Group – A (Fixed dose)

- The fixed dosage of *Uttamamatra* was repeated for the consequent days till *Adhasta Sneha Darshana/Snehodwega/ shamana* of *lakshanas (Shula, Mutradaha, Mutrakrichra, Saraktamutrata)*

Group –B (Increasing dose)

- *Uttama Matra* (24hrs) *Sneha* was calculated everyday based on time taken for digestion of previous day *Sneha* and was administered in increasing dose up to *Adhasta Sneha Darshana / Snehodwega / shamana* of *lakshanas (Shula, Mutradaha, Mutrakrichra, Saraktamutrata)*

***PASCHATA KARMA*:**

Peyadi Samsarjana Krama was advised for 2-3 days.

ASSESSMENT CRITERIA

In the present study the assessment was carried out in the following schedule:
1. Pre-test assessment was done on 0 day before the commencement of intervention.
2. Post test assessment was done on 15th day after the completion of intervention.

SUBJECTIVE PARAMETERS-

1. *Shula*:

table no.1: grading of the *Shula* in *Basti / Nabhi Pradesha*

Grade	Symptoms
0	No Pain in *Basti / Nabhi Pradesha*
1	Mild Pain (Occasionally present in *Basti / Nabhi Pradesha* but not disturb day to day activities)
2	Moderate Pain (Present in *Basti / Nabhi Pradesha* and disturb day to day activity)
3	Severe Pain (Present in both *Basti* and *Nabhi Pradesha*)

2. *Saraktamutrata* (Haematuria):

table no.2: grading of *Saraktamutrata*

Grade	Symptoms
0	No symptoms
1	Mild (presence of 1-9 RBC in urine)
2	Moderate (presence of 10-20 RBC in urine)
3	Severe (presence of more than 20 RBC in urine)

3. *Mutradaha*:

table no.3: grading of *Mutradaha*

Grade	Symptoms
0	No symptoms
1	Mild (burning sensation during urination)
2	Moderate (frequent burning sensation during urination more than 50%)
3	Severe (continuous burning sensation during urination)

4. *Mutrakrichrata*:

table no.4: grading of *Mutrakrichrata*

Grade	Symptoms
0	No symptoms
1	Mild (pain during urination)
2	Moderate (frequent pain during urination more than 50%)
3	Severe (continuous pain during urination)

5. *Mutradhara sanga*

table no.5: grading of *Mutradharasanga*

Grade	Symptoms
0	No symptoms
1	Mild (occasionally obstructed flow of urine during urination)
2	Moderate (frequent obstructed flow of urine during urination more than 50%)
3	Severe (continuous obstructed flow of urine during urination)

OBJECTIVE PARAMETERS:

According To Sonological Findings-

table no.6: scoring of the number of stones

Score	No. Of Stones
1	Single
2	Double
3	Multiple

table no.7: scoring of the size of stone

Score	Size of stone
1	less than 5mm
2	5mm
3	More than 5mm

table no.8: scoring of the site of stone

Score	Site of stone
1	Renal
2	Ureter
3	Bladder
4	Renal + ureter

OVERALL ASSESSESMENT OF CLINICAL IMPROVEMENT:

The sum of the point of all the parameters of assessment before, after treatment was taken into consideration to assess the total effect of the treatment as follows: -

table no.9: overall assessment

Marked improvement	> 75%
Moderate Improvement	50-75%
Mild improvement	25-50%
No improvement	< 25%

The Results were analyzed statistically by using, Paired "t" test, ANOVA Repeated measures as inferential statistics and mean, standard deviation as Descriptive statistics using SPSS for windows software.

OBSERVATIONS

In the present study it was observed that *Mutrashmari* was common in the age group of 20-50 years, males (57.5%) were more affected than females (42.5%), it was mostly observed in people who were more exposed to sunlight (77.5%) and those who had a habit of holding the urge to micturate, incidence was more in middleclass population (85%) and was more in people with mixed diet habits (82.5%). Pain (52.5%) and *Mutradaha* (45%) were the most predominant symptoms observed in the study and other symptoms such as *Mutrakrichra* (37.5%), *Saraktamutrata* (2.5%) and *Mutradharasanga*(22.5%) were observed in very less proportion of the study population.
In the present study, majority of subjects had calculi ranging between 5mm in diameter and single in number.

RESULTS

10 subjects in Group A and 11 subjects in Group B were presented with different grades of pain where both the groups showed statistically significant result on pain with P value 0.004 and 0.002

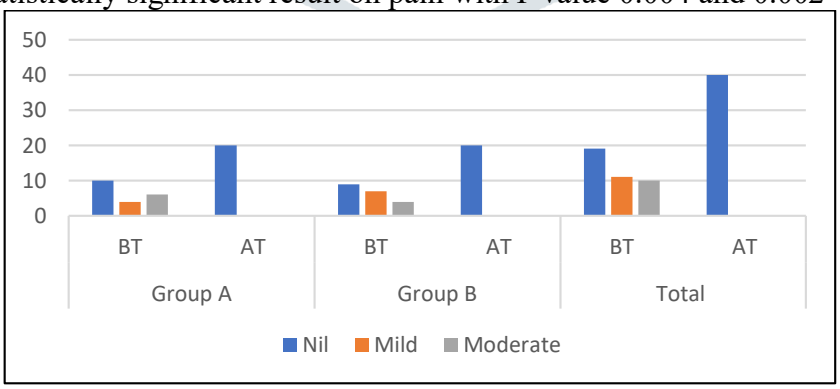

figure n0.1: results on *Shula* in the subjects of *Mutrashmari*

In Group A, 9 subjects had *Mutradaha* where as in Group B, 9 subjects were presented with *Mutradaha* and the results were statistically significance with P value 0.003

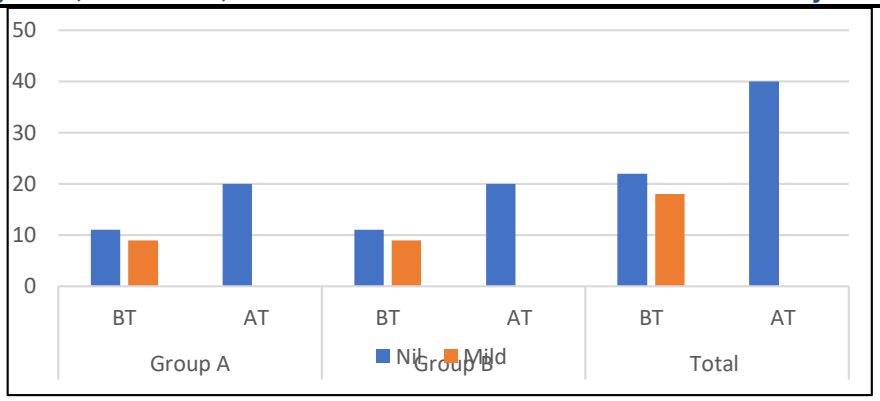

figure n0.2: results on *Mutradaha* in the subjects of *Mutrashmari*

1 subject had mild *Saraktamutrata* in Group B, the result was clinically significant but statistically nonsignificant. No subject in Group A presented with *Saraktamutrata*.

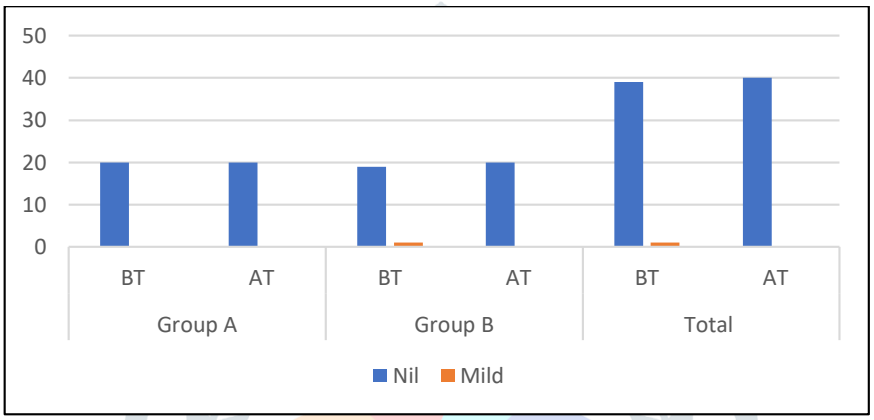

figure n0.3: results on *Sarakta Mutrata* in the subjects of *Mutrashmari*

9 subjects in Group A and 6 subject in Group B were presented with mild and moderate degree of *Mutrakrichra*, the results were statistically significant with the P value 0.005 and 0.020 respectively.

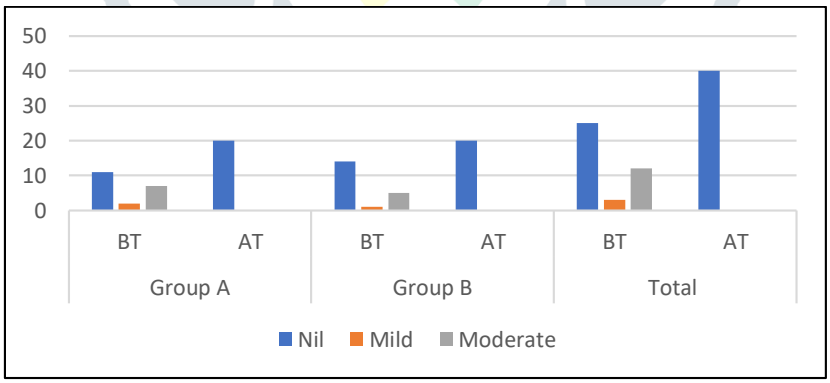

figure n0.4: results on *Mutrakrichra* in the subjects of *Mutrashmari*

4 subjects in Group A and 5 subject in Group B were presented with mild degree of *Mutradharasanga*, the results were statistically significant with the P value 0.46 and 0.025 respectively.

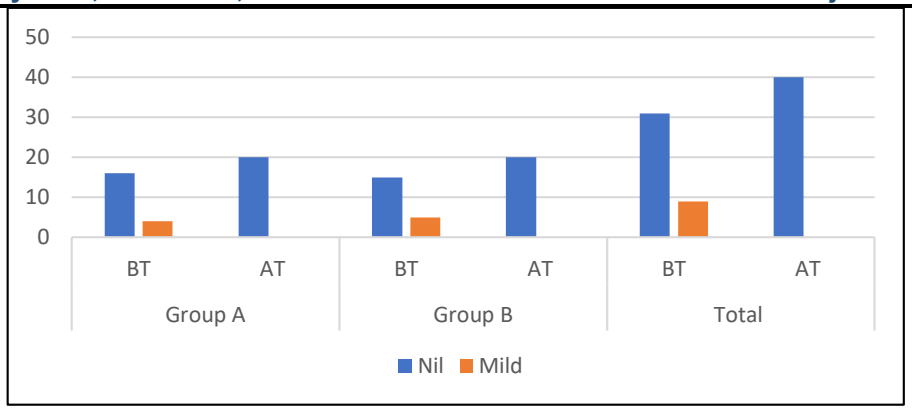

figure n0.5: results on *Mutradhara Sanga* in the subjects of *Mutrashmari*

Result on objective parameters

Number of stones:

In Group A, before intervention, 10(50%) subjects had single calculus, 5(25%) subjects had double calculi, and 5(25%) subjects had multiple calculi. After intervention 7(35%) subjects had single calculus and 1(5%) subject had double calculi and 12(60%) subjects had no calculi. Group A showed statistically highly significant with p value of 0.000.

In Group B, before intervention, 14(70%) subjects had single calculus, 2(10%) subjects had double calculi, and 4(20%) subjects had multiple calculi. After intervention 9(45%) subjects had single calculus and 11(55%) subjects had no calculi. Group B showed statistically highly significant with p value of 0.000.

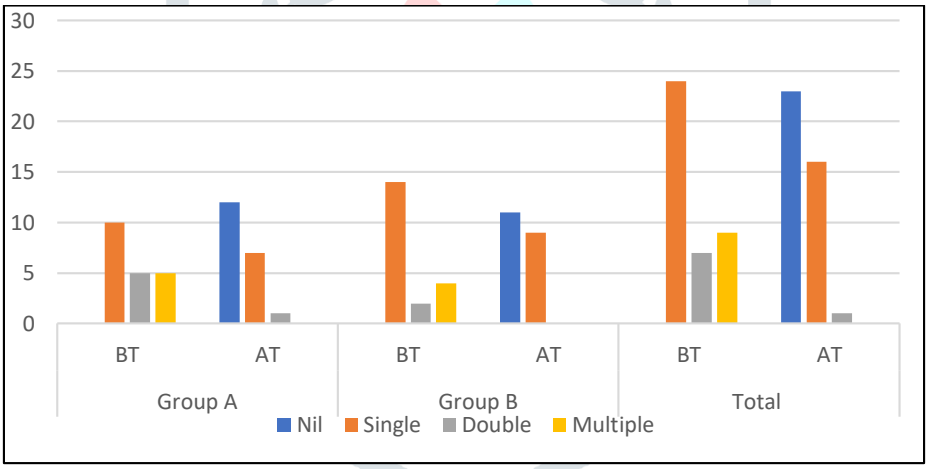

figure n0.6: result on the number of stones

Size of stones:

In Group A, before intervention,11(55%) subjects were detected with size of calculi < 5mm, 9(45%) subjects with size of calculi 5mm were detected. After intervention, in 12(60%) subjects there was no calculi detected, whereas 7(35%) subjects with the calculi of size < 5mm and 1(5%) subject with 5mm calculi. Group A showed highly significance with p value of 0.000.

In Group B, before intervention, 2(10%) subjects were detected with size of calculi < 5mm, 14(70%) subjects with 5mm, and 4(20%) subjects were detected with >5mm calculi. After intervention, in 11(55%) subjects there was no calculi detected, whereas 6(30%) subjects with the calculi of size < 5mm and 3(15%) subjects with 5mm calculi. Group B showed highly significance with p value of 0.000.

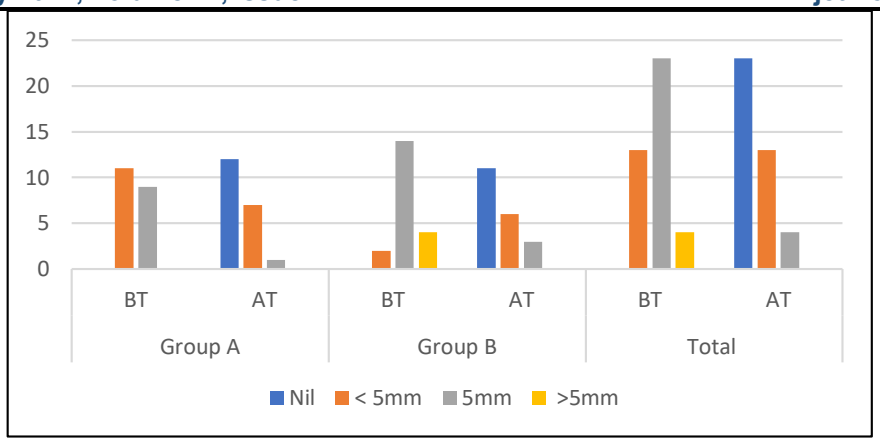

figure n0.7: result on the size of stones

Site of stones:

In Group A, before intervention,17(85%) subjects had stone in kidneys, 1(5%) subject was diagnosed to have ureteric calculi and 2(10%) subject had stone in both kidney and ureter. After intervention, in 12(60%) subjects calculi were expelled, 5(25%) subjects had calculi in kidney and 3(15%) subjects had in ureter. Group A was statistically significant with p value of 0.001.
In Group B, before intervention,16(80%) subjects had stone in kidneys, 1(5%) subject was diagnosed to have ureteric calculi, 1(5%) subject bladder calculi, and 2(10%) subject had stone in both kidney and ureter. After intervention, in 11(55%) subjects calculi were expelled, 5(25%) subjects had calculi in kidney and 4(20%) subjects had in ureter. Group B was statistically significant with p value of 0.014.

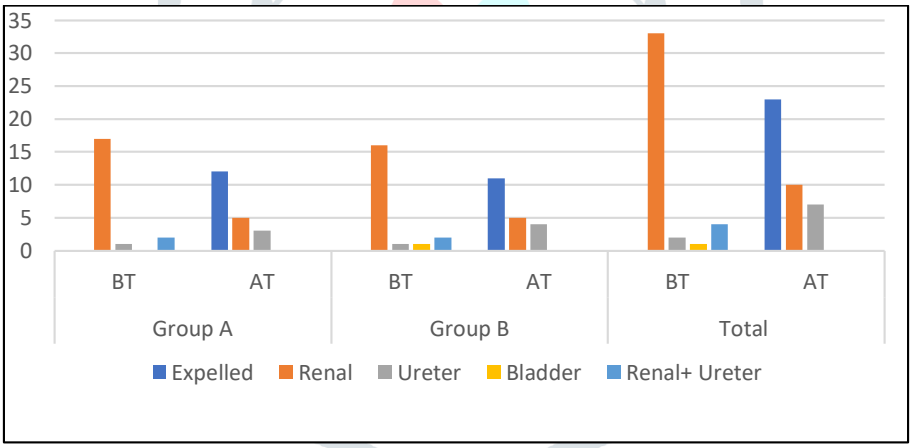

figure n0.8: result on the site of stones

DISCUSSION:

Procedural effect,

- *Avapeedaka Snehapana* is administered in 2 kala at a stretch i.e., *Pragbhakta* (before food) in *Hrusvamatra* and *Ahara Jeernanthaavastha* (after the digestion of food) in *Uttamamatra* respectively.
- As *Ashmari* is one among *Mutravegavarodhajanya Vikara* and it is *Kaphaja Vikara* associated with *Apana* and *Vyana Vata Dushti*.
- *Pragbhakta Sneha* does *Anulomana* of *Apanavayu* and *Shamana* of *Apana Vata*
- *Ahara Jeernanthika Sneha* act on the *Vyana Vata* which is *Sarva Dehachari* and does the *Shamana* of *Vyadhi*. After *Aharapaka*, *Vataadhikya* occurs naturally and the second dose of *Sneha* will mitigate this *Vata*.

Drug effect,

- *Trinapanchamoola Ghrita* having *Madhura*, *Kashay* Rasa Pradhana, *Laghu Snigdha Guna*, *Sheeta Veerya*, *Madhura Vipaka* and *Tridoshahara*. It aids, *Ashmarighna*, *Mutrala*, *Mutavirechaniya* and *Basti Shodhana* properties.

- *Madhura* and *Kashaya Rasa* having *Aap* and *Prithvi Mahabhuta* predominant, which helps the calculus to move downwards due to heaviness of Prithvi and downward moving tendency of *Aap*.
- *Snigdha Guna* and *Madhura Vipaka* increases the urine output and helps in easy passing of stone
- *Mutrala* and *Mutravirechaniya* properties of the drugs causing increased urinary output and are considered to be the best diuretics which helps in flushing out the disintegrated calculi.
- *Ashmarighna* property break the formed stones, expel it from the body.
- *Basti Shodhana* property prevents formation of stones and thereby reduces the chance of recurrence.

table no.10: phytoconstituents and its action

Drug	Phytoconstituent	Action
Kusha	Flavanoid, Cylindrin, Glycosides	Diuretic, Anti-inflammatory, Anti-urolithiatic, Analgesic,
Kasha	Tannin, Galactose, Rhamnose	Anti-lithiatic activity
Nala	Rhamnose, Bufotenine, Tryptamine, rhyzomes	Diuretic, Anti-inflammatory, Anti-spasmodic effect, Hypotensive
Darbha	Cylindrin, arundoin, fernenon	Diuretic, Anti-inflammatory
Kandekshu	Sucrose, Glutamine, Riboflavin	Diuretic, Analgesic activity, Anti-inflammatory
Gokshura	Furosemide, Campesterol, Rhamnose, Beta-sitosterol, Stigmasterol	Diuretic, Anti- urolithic activity, Analgesic, Anti-inflammatory, Anti-spasmodic

CONCLUSION:

In the present study, statistically there is no significant difference between the groups with p value 0.000. Group A showed complete remission in 12 subjects and marked improvement in 7 subjects and moderate improvement in 1 subject whereas Group B showed complete remission in 11 subjects, marked improvement in 6 subjects and moderate improvement in 1 subject. From the above data it can be concluded that, both the groups are equally effective in reducing the size of stones and relieving the symptoms. Till date there is no recurrence of *Mutrashmari* or symptoms of *Mutrashmari* are observed in the subjects involved in the study. With the obtained result it can be concluded that Avapeedaka *Snehapana* with *Trinapanchamooladi Ghrita* can be administered safely and effectively in the management of *Mutrashmari*.

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