COMPARATIVE STUDY OF EFFICACY OF PARNABEEJA SWARAS WITH SHIGRUMOOL KWATH IN MANAGEMENT OF MOOTRASHMARI WITH SPECIAL REFERENCE TO UROLITHIASIS

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ABSTRACT
Ashmari- Urolithiasis is one of the most common diseases found globally. It is found that this condition is having recurrence in-spite of removal of stone by surgical methods in large number of cases. Even after surgical intervention the pathogenesis behind recurrent stone formation cannot be avoided. In Ayurveda, Urinary stone diseases have been described in details under the heading of Ashmari. Ashmari is considered as one among the Ashta-Mahagadas (Eight Fatal diseases). Sushrutacharya, ‘The Father of Surgery’, has described its Etiopathogenesis, Symptomatology, Medical and Surgical treatment and Prognosis in detail. In present study an effort was made to evaluate the role of Parnabeeja (Bryophyllum pinnatum) swaras and Shigrumool kwath in the management of Mootrashmari.

KEYWORDS: Mootrashmari, Parnabeeja swaras, Shigrumool kwath.

INTRODUCTION
Mootrashmari is one of the most distressing diseases among the group of urinary disorders. Lots of work has been done on urolithiasis.

Various treatment modalities are available like PCNL, ESWL, URS, Nephrolithotomy etc. But these are available at higher centres and are too expensive for common people. Even after surgical intervention the pathogenesis behind recurrent stone formation cannot be avoided.
Therefore, it is necessary to find out economical, effective, easily available and acceptable medicine to treat Mootrashmari.

It triggered me to do study in management of Urolithiasis.

AIMS
To compare the efficacy of Parnabeeja Swaras with Shigrumool Kwath in management of Mootrashmari.

OBJECTIVES
1. To find out whether this drug reduces the size of calculus and promotes its expulsion.
2. To study the efficacy of Parnabeeja Swaras in Mootrashmari and comparing it with Shigrumool Kwath.
3. To establish the better medicinal alternative in the management of Mootrashmari.
4. To study Mootrashmari and Urolithiasis in details.

REVIEW OF LITERATURE:

Sushruta has classified the Ashmari into four types
1. Kaphaj
2. Pittaj
3. Vataj
4. Shukraj

MANAGEMENT OF ASHMARI
Following are the treatments of choices in Ashmari -
1. Aushadhi Chikitsa
2. Basti karma
3. Kshara karma
4. Shastra karma

In the present work Aushadhi Chikitsa has been taken for study.
UROLITHIASIS

Urolithiasis means the presence of calculus in the urinary system. It is one of the most common diseases of the urinary tract.

Types of Calculi

a. Primary – Those which appear in apparently healthy urinary tract without any antecedent inflammation these stones are usually formed in acid urine. These stones usually consist of -
   a) Calcium oxalate stones
   b) Uric acid and urate stones
   c) Cystine stones
   d) Xanthine stones

b. Secondary- These stones composed of calcium phosphate though a few are composed of ammonium magnesium phosphate known as triple phosphate these are soft and friable.

Diagnosis

A case of urolithiasis can be diagnosed by-
- History taking
- Plain x-ray K.U.B.
- Ultrasonography
- Intravenous urography
- Retrograde pyelography
- Cystoscopy
- Computerized Tomography

Previous Research Work

• Comparative study of efficacy of Gokshuradi yog and Shigrumool Kwath in the management of Mootrashmari w.s.r. to Urolithiasis. – Dr. Usha Chunade, - MUHS, - 2014.
• A comprehensive review on Parnabeeja [Bryophyllum pinnatum Oken] Journal of Medicinal Plants Studies – ISSN 2320-3862 JMPS 2015
• Bryophyllum pinnatum : A review ISSN 2249-9687

MATERIAL AND METHODS
A clinical trial, ‘Comparative study of Efficacy of Parnabeeja Swaras with Shigrumool kwatha in the management of Mootrashmari’, has carried out in O.P.D. and I.P.D. of our hospital.

METHODOLOGY
It is prospective, randomized, comparative, Open labelled Clinical study. Well diagnosed and randomly selected 70 patients were equally divided into experimental and control group.

MATERIAL
1. Patients suffering from Urolithiasis.
2. Drugs-
   a. Parnabeeja Swaras

   - The fresh juice was extracted daily and administered it to the patients orally, early in the morning for 28 days.

Dosage- 20 ml once a day.

Route of administration- Orally
Time - Apankal (Before meal in morning)
Duration- 28 days
b. Shigrumool Kwatha
- The fresh Kwatha was prepared daily in the morning and evening and administered to the patients of Mootrashmari.
Dosage- 40 ml in lukewarm condition
Route of drug administration- Orally
Time - Aahar raspake (Twice daily before meals)
Duration - 28 days
Selection of Patients

Patients of urolithiasis who attended O.P.D. at our hospital were selected irrespective of sex, education, religion, economical status, occupation etc. by adopting following criteria-

**Inclusion criteria**

1. Patients of *Mootrashmari* with urolith of size 8 mm to 15 mm.
2. Patients of either sex.
3. Age- Between 18 yrs to 60 yrs.
4. Patients of *Mootrashmari* with renal or ureteric calculus.

**Exclusion criteria**

1. The patients having uncontrolled DM, HTN, PTB, Ashtma, etc.
2. The patients having other urinary tract pathologies and impaired renal function.
3. The Pregnant women.
4. The patients having age below 18 years and above 60 years.
5. The patients having stone size below 8 mm. and above 15 mm.
6. Seriously ill patients of other systemic diseases.

Withdrawal Criteria
The patient can be withdrawn from the trial if –
1. Occurrence of serious adverse effects.
2. The protocol has been violated or the patient become uncooperative.
3. The patient is not willing to continue the trial or to follow the assessment schedule.
4. Evidence of any other illness which may interrupt the efficacy of drug.

Investigations
- USG – abdomen and pelvis after preparation
- CBC, BSL®, ESR.
- Urine – Albumin and sugar and microscopic
- KFT- Sr. Creatinine, Blood Urea.

Observational Parameters
1. Size and site of urolith
2. Pain
3. Burning Micturition
4. Haematuria

Subjective Parameters
- Pain- Present = 1 Absent = 0
- Burning Micturition- Present = 1 Absent = 0
- Haematuria- Present = 1 Absent = 0

Follow Up
- Patients will be observed in each follow up on 0th, 7th, 14th, 21st and 28th day.
- The size and site of urolith will be observed by USG on 0th, 14th and 28th day.
- Other investigations will be done at 1st visit and after 28th day.
STUDY DESIGN

Screening of subject for inclusion
| Initial assessment & selection of patients
| Group allocation by randomization
  Group A (Trial Group)  Parnabeesha Swaras
  Group B (Control Group)  Shigruuool Kwatha
  Assessment on 0th 7th 14th 21th 28th days
| Collection, classification & presentation of data
| Statistical analysis
| Conclusion

Sample Size Calculation
Calculation of sample size by Danniel 1999.
Where,
\[ z = 1.96 \text{ statistical level of significance}. \]
\[ p = 10\% \text{ overall prevalence i.e. } 0.1 \]
\[ (1-p) = 1-0.1 = 0.9 \]
\[ d = \text{allowable error } 10\% \text{ hence } d = 0.1 \]
by calculating,
\[ n = \frac{1.96^2 \times 0.1 (0.9) = 34.57}{(0.1)^2} \]
So for sake of our convenience 35 patients will be taken in each group.

Criteria For Assessment Of Result
1. Cured - If stone expelled out from Urinary tract.
2. Improved - If stone size reduced or it moves from upper site to lower site.
3. Not cured - If stone size increases or there is no change in size and Site of urolith.
OBSERVATIONS AND RESULTS

- 70 patients, were equally divided into trial and control group and statistically analysed.
- The objective parameters size and site of the urolith and subjective parameters pain, burning micturition and haematuria were recorded at each follow up. The result was drawn on the basis of the completion of treatment. The level of significance was set at 5% (P=0.05).
- The primary response variable parameter difference in size of urolith was analysed by applying ‘Z’ test. The site of urolith was analysed by chi square test. The subjective parameters pain, burning micturition and haematuria were analysed by applying chi square test.

Subjective parameters

Follow up wise effect of treatment on pain:

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Group</th>
<th>No</th>
<th>Yes</th>
<th>$\chi^2$</th>
<th>P</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>7th day</td>
<td>Trial</td>
<td>08</td>
<td>27</td>
<td>0.2991</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>10</td>
<td>25</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td>14th day</td>
<td>Trial</td>
<td>16</td>
<td>19</td>
<td>0.0579</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>15</td>
<td>20</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td>21st day</td>
<td>Trial</td>
<td>20</td>
<td>10</td>
<td>0</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>20</td>
<td>10</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td>28th day</td>
<td>Trial</td>
<td>30</td>
<td>05</td>
<td>0.1275</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>31</td>
<td>04</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
</tbody>
</table>

Follow up wise effect of treatment on Burning micturition:

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Group</th>
<th>No</th>
<th>Yes</th>
<th>$\chi^2$</th>
<th>P</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>7th day</td>
<td>Trial</td>
<td>14</td>
<td>21</td>
<td>0.2448</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>12</td>
<td>23</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td>14th day</td>
<td>Trial</td>
<td>20</td>
<td>15</td>
<td>0.0579</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>19</td>
<td>16</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td>21st day</td>
<td>Trial</td>
<td>27</td>
<td>08</td>
<td>0.2991</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>25</td>
<td>10</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td>28st day</td>
<td>Trial</td>
<td>31</td>
<td>04</td>
<td>0.1275</td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
<tr>
<td>(BT-AT)</td>
<td>Control</td>
<td>30</td>
<td>05</td>
<td></td>
<td>P&gt;0.05</td>
<td>35</td>
</tr>
</tbody>
</table>

Follow up wise effect of treatment on Burning micturition:
Follow up wise effect of treatment on Haematurea

<table>
<thead>
<tr>
<th>Follow up</th>
<th>Group</th>
<th>No</th>
<th>Yes</th>
<th>$\chi^2$</th>
<th>P</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>7th day</td>
<td>Trial</td>
<td>27</td>
<td>08</td>
<td>0.0848</td>
<td>P&gt;0.05</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>28</td>
<td>7</td>
<td></td>
<td>P&gt;0.05</td>
<td>18</td>
</tr>
<tr>
<td>14th day</td>
<td>Trial</td>
<td>30</td>
<td>5</td>
<td>0.0515</td>
<td>P&gt;0.05</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>35</td>
<td>5</td>
<td></td>
<td>P&gt;0.05</td>
<td>18</td>
</tr>
<tr>
<td>21st day</td>
<td>Trial</td>
<td>27</td>
<td>8</td>
<td>1.6092</td>
<td>P&gt;0.05</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>Control</td>
<td>31</td>
<td>4</td>
<td></td>
<td>P&gt;0.05</td>
<td>18</td>
</tr>
<tr>
<td>28th day</td>
<td>Trial</td>
<td>32</td>
<td>3</td>
<td>0.1587</td>
<td>P&gt;0.05</td>
<td>17</td>
</tr>
<tr>
<td>(BT-AT)</td>
<td>Control</td>
<td>31</td>
<td>4</td>
<td></td>
<td>P&gt;0.05</td>
<td>18</td>
</tr>
</tbody>
</table>

OBJECTIVE CRITERIA

1. Effect of treatment on size of urolith.

<table>
<thead>
<tr>
<th>Follow Ups</th>
<th>Trial Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$\bar{x}$</td>
<td>SD</td>
</tr>
<tr>
<td>0th day</td>
<td>10.12</td>
<td>1.938</td>
</tr>
<tr>
<td>14th day</td>
<td>9.600</td>
<td>1.931</td>
</tr>
<tr>
<td>28th day</td>
<td>8.891</td>
<td>0.4383</td>
</tr>
</tbody>
</table>

The above table shows the follow up wise decrease in size of urolith in both group. Where,

$\bar{x}$ - Mean

SD - Standard deviation

SE - Standard error.\textsuperscript{[2]}

Comparison of effect of treatment on size of urolith in Control group and Trial group:

<table>
<thead>
<tr>
<th>Groups</th>
<th>$\bar{x}$</th>
<th>SD</th>
<th>SE</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group(BT-AT)</td>
<td>3.729</td>
<td>3.979</td>
<td>0.6725</td>
<td>3.5041</td>
<td>P&lt;0.05</td>
</tr>
<tr>
<td>Trial group(BT-AT)</td>
<td>1.220</td>
<td>1.453</td>
<td>0.2456</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Where

$\bar{x}$ - Difference of mean

SD - Difference of standard deviation

SE - Difference of standard error.

The above table shows that the value of ‘Z’ is more than 1.96 and it is significant. The mean reduction in size of urolith is more in Control group than Trial group. The ‘Z’ value suggest that the Control group is more significant than the Trial group.
No. of patients Cured/Improved/Not cured after treatment (28 days):

<table>
<thead>
<tr>
<th>Result</th>
<th>Trial</th>
<th>%</th>
<th>Control</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>1</td>
<td>02.86</td>
<td>12</td>
<td>34.29</td>
</tr>
<tr>
<td>Improved</td>
<td>31</td>
<td>88.57</td>
<td>19</td>
<td>54.29</td>
</tr>
<tr>
<td>Not cured</td>
<td>3</td>
<td>08.57</td>
<td>4</td>
<td>11.42</td>
</tr>
<tr>
<td>Total</td>
<td>35</td>
<td>100</td>
<td>35</td>
<td>100</td>
</tr>
</tbody>
</table>

**DISCUSSION**

1. **Pain**

Pain was observed at each follow up and it was found that there was significant reduction in pain in both groups.

The chi square values are insignificant at each follow up, so it conclude that both drugs are effective in reducing the pain. But out of 32 patients in trial group 27 (84.38%) patients were relived from pain where as in control group out of 30 patients 26 (86.67%) were relieved from pain at the end of treatment. It indicates that the Control drug is effective than Trial drug.

2. **Burning Micturition**

It was observed at each follow up and found that there was significant reduction in Burning micturition in both groups. The chi square value is insignificant at each follow up, so it conclude that both drugs are effective in reducing the Burning micturition.

But out of 28 patients in trial group 24 (85.71%) patients were relieved from Burning micturition. In control group out of 26 patients 21(80.77%) were relieved from Burning micturition at the end of treatment. It indicates that the trial drug is slight effective than control drug.

3. **Haematuria**

It was observed at each follow up. It was found that there was significant reduction in Haematuria in both groups. The chi square value is insignificant at each follow up, so it conclude that both drugs are effective in reducing the Haematuria. Out of 10 patients in trial group 07 (70%) patients were relieved from Haematuria where as in control group out of 8 patients 04 (50%) were relieved from Haematuria at the end of treatment. It indicates that the trial drug is more effective than control drug.
OBJECTIVE CRITERIA

1) Size
As per USG findings the reduction in size of urolith observed and it was found significant in both groups. At the end of treatment the ‘Z’ value of trial group (BT-AT) is 2.246 and of control group (BT-AT) is 4.2169.

Both values are significant so ‘Z’ test was applied to the difference values of before and after treatment of Control and trial groups. The value is 3.5041, that is significant, so it concludes that Control drug is more effective in reducing the size of urolith than Trial drug.

2) Site
As per the USG findings the effect of treatment on the site of stone is assessed. Out of 25 patients of kidney stone from trial group, no one cured and out of 27 patients in control group 4 (14.81%) were cured.

Out of 10 patients of ureteric stones 1 (10%) patient was cured in trial group while in control group out of 8 patients 8 (100%) were cured. So it concludes that control drug is more effective in reducing the size of stone than trial drug in kidney as well as in patients having ureteric stones.

It indicates that the Shigrumool kwath is more effective in dissolution as well as in expulsion of stone than Parnabeeja Swaras.

CONCLUSION
Parnabeeja swaras as well as Shigrumool kwath both are effective in reducing the clinical features and size of stone. But the Shigrumool kwath is more effective than Parnabeej swaras in dissolving and expulsion of kidney stone (Nephrolithiasis) as well as ureteric stone (Ureterolithiasis).

So it can be concluded that the Shigrumool kwath is more effective in the management of moottrashmari (Urolithiasis).
SUMMARY

- Well diagnosed 70 patients having urolithiasis were randomly selected and equally divided in both trial and control groups.
- Special case record form was prepared and clinical features of patients were recorded at each follow up.
- Size and site of urolith was recorded at each follow up as seen in U.S.G. report.
- Patients were treated in OPD without hampering other routine work.
- *Parnabeeja swaras* and *Shigrumool kwath* were prepared as per standard preparation method of preparation.
- Drug analysis done.
- The obtained data was statistically analysed by applying appropriate tests.
- Both drugs are statistically significant to reduce the size and clinical features of urolith but drug of control group is more effective than trial group.

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THESIS