AN AETIOPATHOLOGICAL STUDY OF ASHMARI (URINARY CALCULUS) & A RANDOMIZED CONTROLLED UPASHAYATMAKA TRIAL TO EVALUATE THE ASHMARIGHNA EFFECT OF SHVADAMSHTRADI & VARUNADI KVATHA

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ABSTRACT

Mutrashmari is one of the most common urinary disorders. Acharya Sushruta, the pioneer in the art and science of surgery has described widely and comprehensively about Mutrashmari along with its classification, symptomatology, etiology, pathology, complications and its management. This disease is dreadful and hence considered as one of the ‘Mahagada’ by Sushruta, may be owing to its potentiality to disturb the anatomy and physiology of urinary system. The main aim of this study is to summarize the management of Mutrashmari with herbal formulations and dietary & lifestyle inventions; to understand the Ayurvedic concept of Mutrashmari (urolithiasis).

Keywords: Ashmari, Shvadamshtradi & Varunadi Kvatha.

INTRODUCTION

Ayurveda, the system of Indian medicine and science of life deals with the well being of mankind. The three great authors namely Charaka, Sushruta and Vagbhatta followed the scientific methods of study to enhance the perception of Ayurveda towards humanity. Sushruta the father of surgery explained urinary calculus under the heading of Ashmari in details including etiological factors, classification, symptomatology, pathology, complications and its management in a most scientific manner. This disease is dreadful and hence considered one of the ‘Mahagada’ by Sushruta, may be owing to its potentiality to disturb the anatomy and physiology of urinary system.

Mutrashmari is one of the most common urinary disorders. Formation of urinary calculi is described in Ayurvedic scriptures as Mutrashmari. The diagnostic part in case of calculi by ancient Acharya seems to be true even at present. Formation of Mutrashmari, according to Sushruta, is due to Sroto Vaigunya resulting from Dushita Kapha localized in Basti, in conjunction with Pradushita Vata and Pitta.

Need for the study: Treatment of this disease is mainly Shalya Karma, which is difficult procedure & every surgery which is either minor or major has many risk factors and in some cases even life is endangered and in surgery even a well equipped and experienced surgeon’s success is also uncertain. Surgical techniques are costly and as India is a developing country and a large number of population lives under the poverty line so for these persons; treatment of Mutrashmari by these methods is not affordable, and one another main problem
with this disease is that after the complete removal of the Mutrashmari it cannot be said that patient will remain fit for a long time because in this disease recurrence rate is very high. Thus keeping all these points in mind it is necessity of today that a detailed study of an aetiopathology of this disease should be done, and by applying that knowledge healthy people should be educated so that they can remain away from this disease, and second motive of this work is to find a drug which can eliminate the stone in the patient of Mutrashmari at a very low and affordable cost.

**Aims & Objectives:** To conduct a randomized controlled Upashayatmaka trial to evaluate the Ashmarighna Effect of Shvadamshtradi Kvatha and Varunadi Kvatha.

**Material and Method:** It was a prospective randomized controlled trial. Pre diagnosed and diagnosed patients of Ashmari were selected for Upashayatmaka (clinical) trial from the OPD & IPD of the NIA, hospital. Selection was carried out according to relevant history, signs and symptoms including laboratory investigations and the patients giving written informed consent to participate in the clinical trial were selected for the Upashayatmaka study. Total 34 patients were registered out of which only 30 patients completed the study. Patients were divided into 2 groups. In Group A; 15 patients were treated by Shvadamshtradi Kvatha and in Group B; 15 patients were treated by Varunadi Kvatha.

**Design of study:**

- **Type of study:** Simple randomized comparative clinical trial.
- **No. of group:** 2, **No. of patients:** 30
- **Duration of trial:** 1 month.
- **Follow-up period:** Patients were examined for the change in the signs and symptoms on 15th, & 30th day of treatment.

**Inclusion Criteria for Clinical Trial:**
1. Patients having clinical features of Ashmari as described in Ayurvedic classics.
2. Pts. of age between 18-50 yrs. with signs & symptoms of Ashmari.
3. Calculus (i) 6-8 mm size.
4. Patients belong to either gender, irrespective of religion, sex, socio-economic status, occupation are included for the study.

**Exclusion Criteria:**
1. Uncooperative patients.
2. Patients suffering from major illness like T.B., cancer, HIV/AIDS.
3. Age < 18yrs. & Age >50yrs. will be excluded from the study.
4. Pregnant ladies and lactating mothers.

**Withdrawal criteria:**
If any patient develops any adverse reaction or deterioration in condition, or could not report for regular follow up during clinical trial due to any reasons, he/she was withdrawn from the trial.

**Preparation of trial drugs:** Both formulations Shvadamshtradi Kvatha and Varunadi Kvatha were prepared as per the standard guidelines under the supervision of the subject experts in the pharmacy of NIA, Jaipur.

**Treatment schedule:** Total 30 patients were registered and randomly divided into two groups, each group contains 15 patients.

**Group A:** 15 patients were treated by Shvadamshtradi Kvatha (40 ml) twice a day.

**Group B:** 15 patients were treated by Varunadi Kvatha (40 ml) twice a day.

**Clinical signs & symptoms viz 5** - Nabhi Vedana, Basti Vedana, Sevani Vedana, Mehana Vedana, Mutradhara Samga, Sarudhira Mutrata (Haematuria), Gomeda-prakshama, Atyavilamutrata, Burning
micturition. Dysuria, Tenderness in renal angle.

**Laboratory investigations:**
Ultra sonography of KUB region,
Urine examination (Routine and microscopic)
Serum creatinine and Blood urea
CBC
ESR

**Criteria for total effect of therapy:**
For the assessment of the total effect of the therapy following four categories were taken into considerations.

- **Cured** – 76% to 100%
  - Complete relief in subjective signs and symptoms.
  - Absence of any calculus in urinary tract with radiological evidence.
- **Markedly Improved** – 51% to 75%
  - Relief in subjective signs and symptoms.
  - Downward movement or partial disintegration of *Mutrashmari* with radiological evidence.
- **Improved** – 26% to 50%
  - Relief in signs and symptoms.
  - Without any change in size of stone confirmed with radiological evidence.
- **Unchanged** – Up to 25%
  - Relief in subjective sign and symptoms.

**Clinical assessment:**

**Demography of general profile:** It includes incidence of age, sex, marital status, education, occupation, economical status, dietary habits, & addictions etc.

**Demography of clinical profile:** It includes incidence of family history, associated symptoms, *Dashavidha Pariksha* etc.

**Statistical analysis:**
All the calculations were calculated through 'Graph Pad Instat' Software.

- **Paired’ test**- Applied to independent observation from one sample only when each individual gives a pair of observation, for parametric assessment. It was used on objective parameter of all the two groups A & B.
- **Wilcoxon signed rank test**- Non parametric test for the case of two related samples or repeated measurement on a single test. It was used for the assessment of improvement in symptom of group A & B.
- **Intergroup comparison:** For subjective parameters ‘Mann Whitney U- Statistic test’ was applied and in objective parameters results were assessed by applying unpaired’ test.

**Observations and Results:** In this study patients were treated in two individual groups *Shvadamshtradi Kvatha* (Group A) and *Varunadi Kvatha* (Group B). The results were drawn as under on all symptoms of each individual at the end of entire course.

**Table1: Showing the % of symptomatic improvement in 30 patients in 2 groups:**

<table>
<thead>
<tr>
<th>S.No.</th>
<th>Symptomatic improvement</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Nabhi Vedana</td>
<td>82.61</td>
<td>85.71</td>
</tr>
<tr>
<td>2</td>
<td>Basti Vedana</td>
<td>70</td>
<td>76.92</td>
</tr>
<tr>
<td>3</td>
<td>Sevani Vedana</td>
<td>50</td>
<td>62.50</td>
</tr>
<tr>
<td>4</td>
<td>Mehana Vedana</td>
<td>50</td>
<td>66.67</td>
</tr>
<tr>
<td>5</td>
<td>Mutradhara Samga</td>
<td>84.21</td>
<td>83.33</td>
</tr>
<tr>
<td>6</td>
<td>Sarudhira Mutrata (Haematuria)</td>
<td>50</td>
<td>66.67</td>
</tr>
</tbody>
</table>
Table 2: Effect of therapy on types of Ashmari in 30 patients

<table>
<thead>
<tr>
<th>Variety/Effect</th>
<th>Group I</th>
<th></th>
<th>Group II</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of pts.</td>
<td>%</td>
<td>No. of pts.</td>
<td>%</td>
</tr>
<tr>
<td>Vaṭaja  Ashmari</td>
<td>12</td>
<td>80%</td>
<td>13</td>
<td>86.66%</td>
</tr>
<tr>
<td>Cured</td>
<td>07</td>
<td>58.33%</td>
<td>10</td>
<td>76.92%</td>
</tr>
<tr>
<td>Markedly Improved</td>
<td>05</td>
<td>41.66%</td>
<td>03</td>
<td>23.07%</td>
</tr>
<tr>
<td>Unchanged</td>
<td>00</td>
<td>00%</td>
<td>00</td>
<td>0%</td>
</tr>
<tr>
<td>Pittaja  Ashmari</td>
<td>01</td>
<td>6.66%</td>
<td>01</td>
<td>6.66%</td>
</tr>
<tr>
<td>Cured</td>
<td>00</td>
<td>00%</td>
<td>01</td>
<td>100%</td>
</tr>
<tr>
<td>Markedly Improved</td>
<td>01</td>
<td>100%</td>
<td>00</td>
<td>0%</td>
</tr>
<tr>
<td>Unchanged</td>
<td>00</td>
<td>00%</td>
<td>00</td>
<td>0%</td>
</tr>
<tr>
<td>Kaphaja  Ashmari</td>
<td>02</td>
<td>13.33%</td>
<td>01</td>
<td>6.66%</td>
</tr>
<tr>
<td>Cured</td>
<td>01</td>
<td>50%</td>
<td>00</td>
<td>0%</td>
</tr>
<tr>
<td>Markedly Improved</td>
<td>01</td>
<td>50%</td>
<td>01</td>
<td>100%</td>
</tr>
<tr>
<td>Unchanged</td>
<td>00</td>
<td>00%</td>
<td>00</td>
<td>0%</td>
</tr>
</tbody>
</table>

Table 3: Effect of therapy on the basis of site in 30 patients of Mutrashmari

<table>
<thead>
<tr>
<th>Variety/Effect</th>
<th>Group I</th>
<th></th>
<th>Group II</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of pts.</td>
<td>%</td>
<td>No. of pts.</td>
<td>%</td>
</tr>
<tr>
<td>Kidney stone</td>
<td>11</td>
<td>73.33%</td>
<td>12</td>
<td>80%</td>
</tr>
<tr>
<td>Cured</td>
<td>06</td>
<td>54.54%</td>
<td>09</td>
<td>75%</td>
</tr>
<tr>
<td>Markedly Improved</td>
<td>05</td>
<td>45.45%</td>
<td>03</td>
<td>25%</td>
</tr>
<tr>
<td>Ureteric stone</td>
<td>02</td>
<td>13.33%</td>
<td>01</td>
<td>6.66%</td>
</tr>
<tr>
<td>Cured</td>
<td>01</td>
<td>50%</td>
<td>01</td>
<td>100%</td>
</tr>
<tr>
<td>Markedly Improved</td>
<td>01</td>
<td>50%</td>
<td>00</td>
<td>0%</td>
</tr>
<tr>
<td>Bladder stone</td>
<td>02</td>
<td>13.33%</td>
<td>02</td>
<td>13.33%</td>
</tr>
<tr>
<td>Cured</td>
<td>01</td>
<td>50%</td>
<td>01</td>
<td>50%</td>
</tr>
<tr>
<td>Markedly Improved</td>
<td>01</td>
<td>50%</td>
<td>01</td>
<td>50%</td>
</tr>
</tbody>
</table>

Objective Parameters:

Table 4: Effect of therapy on 30 patients of Mutrashmari

<table>
<thead>
<tr>
<th>Variable</th>
<th>Grp A</th>
<th>Mean B.T.</th>
<th>Diff</th>
<th>% Relief</th>
<th>SD±</th>
<th>SE±</th>
<th>t</th>
<th>P</th>
<th>S</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of</td>
<td></td>
<td>2.07</td>
<td>.80</td>
<td>1.27</td>
<td>61.29</td>
<td>.80</td>
<td>.21</td>
<td>6.141</td>
<td>&lt;.0001</td>
</tr>
</tbody>
</table>
From the above observations it can be summarized that Varunadi Kvatha having better effect in kidney and ureteric stones in comparison to Shvadamshtradi Kvatha. It might be due to Guda with its Mutrala and Yavakshara with its Lekhana, Shodhana and Bhedana properties may have reduced the size of the stone and made them easy to expel out.

- Total effect of therapies: In Group A: Screening of total effect of therapy revealed that out of 15 patients, 53.33% were cured and 46.67% were markedly improved. In Group B: Screening of total effect of therapy revealed that out of 15 patients, 73.33% were cured and 26.67% were markedly improved. So, it can be concluded that the group B (Varunadi Kvatha) is found to be more effective in comparison to group A (Shvadamshtradi Kvatha).

**DISCUSSION**

The aim and objective of investigation is to reach up to a definite conclusion by understanding the concepts into their correct manner. Study of any concept under various heading gives it complete orientation, but correct understanding and proper interpretation of the concept helps to achieve the determined goal and it is possible only with the discussion.

So, as pointed out earlier that the present research work aims to undertake “An aetiopathological study of Ashmari (Urinary Calculus) & a randomized controlled Upashayatmaka trial to evaluate the Ashmarighna effect of Shvadamshtradi & Varunadi Kvatha”, and to draw a hypothesis regarding the mode of action of the drugs used in the present clinical trial on the scientific basis.

- Probable mode of action of drug compound: For the manifestation of the disease ‘Ashmari’, the ‘Kapha Dosha’ is the main factor, which contributes the nucleus for the pathogenesis. It can be clarified that Kapha is essential for Ashmari formation, because Kapha possess Prithvi Mahabhuta and also having the property of Bandhana. It is also a known fact, that when the urine becomes stagnated in the urinary system for long time, it gets concentrated and infected. For that, the main motto of the treatment must be Kaphahara, Vatanulomana, Vedanasthapana, Bhedana and Mutrala.

These formulations taken for the study are indicated in ‘Ashmari Roga’ by the author of ‘Cakradutta’.
Shvadamsshradi Kvatha: Shvadamsshradi Kvatha contains Gokshura, Eranda, Shunthi and Varuna. The compound possesses all the needful actions like Mutrala, Ashmarighna, Vedanasthapana, Dipana, Shothahara, Bhedana. Thus the Shothahara and Mutrala properties of ingredients help to relieve pain and Sthanika Shotha. Jvara is also relieved due to the Jvarahara action of Varuna and Shunthi. Dipana property of drug helps to increase the Agni, which further check the formation of Ama at Jatharagni level itself. Pachana property of ingredients helps in assimilations of drug in the body in case of Jatharagnimandya. Due to the Ashmari Bhedana or Ashmarihara property of ingredients present in the drugs, stone might be dissolved.

Varunadi Kvatha: It contains Varuna, Shunthi, Gokshura, Yavashara and Guda. The ingredients of Varunadi Kvatha are having all needful actions like; Kaphahara, Lekhana and Mutrala. The ingredients of the compound pacifies Kapha Dosh by virtue of their Rudsha Guna, Katu Vipaka and Ushna Virya and also shows Lekhana property due to Ushna Virya. The Lekhana Karma is again enhanced by famous Lekhana Dravya i.e. Yavakshara, which is one of the ingredient. Yavakshara and Gu a have cumulative effect as Ashmari Bhedana, Mutrala and Yavakshra with its Lekhana, Shodhana etc. properties may have reduced the size of the stone and made them easy to expel out.

All the ingredients in both Shvadamsshradi Kvatha and Varunadi Kvatha are having a particular mode of action on Dosh Dushya, Agni and Srotasa. The properties of the ingredients like Vedanasthapana, Vatanulomana, Daha Prashamana, Bhedana, Shothahara, Medohara, Mutrala, Mutra Virechaniya, Dipana, Pachana act on the Dosa (Vata, Pitta and Kapha), Dushya (Rasa, Mutra), Srotasa (Mutravaha Srotasa) and Agni.

CONCLUSION:
- Varunadi Kvatha (Group B) showed better percentage relief in following: Subjective parameters- Vedana, Saurudhira Mutrata, Gomedaparakshama, burning micturition, dysuria, and tenderness in renal angle & in all objective parameters; while Shvadamsshradi Kvatha (Group A) showed better percentage relief in Mutradhara Samga and Atyavamutrata.
- This is clear from the above discussion that improvement was found in both groups, but it was more in group B (Varunadi Kvatha) in comparison to group A (Shvadamsshradi Kvatha)

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