A CLINICAL STUDY TO EVALUATE THE EFFICACY AND SAFETY OF GOKSHUR EXTRACT CAPSULE IN RENAL CALCULUS

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ABSTRACT

Kidney stones [renal calculi] are solid concretions formed in the kidney from dissolved urinary minerals. The incidence of renal calculi ranges from 55-60\% in males and 40-45\% in females. The most advanced non-invasive surgical procedure in conventional therapy like lithotripsy developed certain complications in later period. Hence there is an urgent need to look into an alternative method to treat renal calculi. For this reason, a single blind placebo controlled clinical study is conducted on 200 patients attending the OPD of Shalyatantra, at Govt. Astang Ayurvedic College, Indore, Madhya Pradesh, India diagnosed with renal calculus. They were randomly allotted into two groups i.e. Group A and Group B comprising 100 patients in each. Two capsules of Gokshura extract of 500 mg each were given thrice daily for group A and two capsules of sugar powder of 500 mg each were given thrice daily for group B. Results were assessed based on the improvement in the clinical features, laboratory and radiological investigations. In this study, 62.63, 86.74, 86.66 and 91 percent of the subjects were completely relieved of symptoms of frequency of micturition, dysuria, haematuria and intermittent colicky pain in Group A. 95.12 and 84.74 percent of the subjects of Group A were found with absence of calculi through radiological investigation after treatment with sizes 4-6 mm and 7-10 mm before treatment respectively. In Group B, there was no considerable relief in either the symptoms or in the expulsion of stone. No adverse drug reactions were observed during or after the study. Hence it can be concluded that the Gokshura extract capsules were effective and safe in the cure of renal calculus as compared with the sugar powder capsules.

Key words: Renal calculi, Gokshura.

INTRODUCTION

Kidney stones [renal calculi] are solid concretions formed in the kidney from dissolved urinary minerals. The incidence of renal calculi ranges from 55-60\% in males and 40-45\% in females. Among the various types of calculi, the prevalence of Calcium stones is 75-85\%, uric acid stones 5-6\%, cysteine stones 21\% and struvite stones 10-15\%. The majority of calcium stones comprise of calcium-oxalate stones followed by calcium phosphate stones. Some people with metabolic abnormalities may produce uric acidstone and cysteine stone.

Kidney stone typically leave the body by the passage in urine stream and many stones are formed and passed without causing symptoms. If stones grow more than 2-3 mm they can cause dilation and stretching of upper ureter and renal pelvis as well as muscle spasm of ureter, trying to move stones. It causes renal colic which is...
associated with nausea and vomiting. There can be blood in urine also.

The non-invasive surgical procedure of Conventional therapy like lithotripsy developed diabetes 3.75 times and hypertension 1.47 times than those whose kidney stone were treated with other methods.

To overcome this, there is an urgent need to peep into alternative systems of medicine for safe, effective and economical therapies. Ayurveda, an indigenous Indian system offers vast scope for the successful treatment for urinary tract problems like renal calculus. Acharya Charak and Sushruta identified a disease named Asmari. It is mentioned in Ashta Mahagadas. Slesmaasmari described in Ayurveda resembles with calcium phosphate stone, Pitta asmari with uric acid stones and Vata asmari with calcium oxalate stone. Large numbers of indigenous drugs are mentioned for the treatment. Hence there is a need for systematic investigation and evaluation of their efficacies.

**Aims and objectives**

To evaluate the efficacy and safety of Gokshura extract capsules in renal calculus.

**Materials and methods**

**Subjects**

Patients attending the OPD of Shalyatantra at Govt. Astang Ayurvedic College, Indore Madhya Pradesh, India, were diagnosed with renal calculus. They were randomly allotted into two groups i.e. Group A and Group B consisting of 100 patients in each.

**Inclusion criteria**

Patients aged between 20 to 60 years of either sex with the complaint of the following signs and symptoms.

- Haematuria
- Dysuria
- Frequency of micturition
- Colicky pain
- Evidence of calculus more than 4mm up to 10mm in either X-ray KUB or USG KUB region.

**Exclusion criteria**

Patients with hypertension, severe UTI, Hydro nephrosis, pyelonephrosis and chronic renal failure

**Criteria for withdrawal**

If any adverse events developed during course of the treatment

**Drug administration**

Two capsules of Gokshura extract of 500 mg each were given thrice daily for group A and two capsules of sugar powder of 500 mg each were given thrice daily for group B for three months.

**Drug preparation**

Dry fruits of Gokshura were pounded to coarse powder and water is added in the ratio of 1:8. It was boiled till ¼ of it is remained. It was filtered and the kwatha was boiled till the evaporation of water and dried. Dry Gokshura panchang is collected and powdered. 100 mg of dried extract powder and 400 mg of panchang powder is filled in the empty capsules. They were administered for group A. Sugar was powdered. It was filled in empty capsules and was administered for group B.

**Routine Examination and assessment**

Patients were informed of the study design thoroughly. A detailed history was taken, the data on physical examination, laboratory investigation were recorded monthly and assessment was made. X-ray KUB or USG KUB was done before treatment and after treatment.

**Criteria for the assessment of results**

Results were assessed based on the improvement in the clinical features, laboratory and radiological investigation.

A scoring system was adopted for gradation of severity of the disease as 3, 2, 1 respectively for severe moderate and mild
nature of symptoms while 0 was regarded as absence of symptoms.

**Observations and Results**

<table>
<thead>
<tr>
<th>Age in yrs</th>
<th>Group A</th>
<th></th>
<th>Group B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>21-30</td>
<td>Male</td>
<td>12</td>
<td>12</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>06</td>
<td>06</td>
<td>Female</td>
</tr>
<tr>
<td>31-40</td>
<td>Male</td>
<td>28</td>
<td>28</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>13</td>
<td>13</td>
<td>Female</td>
</tr>
<tr>
<td>41-50</td>
<td>Male</td>
<td>22</td>
<td>22</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>12</td>
<td>12</td>
<td>Female</td>
</tr>
<tr>
<td>51-60</td>
<td>Male</td>
<td>3</td>
<td>3</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>04</td>
<td>04</td>
<td>Female</td>
</tr>
<tr>
<td>Total</td>
<td>Male</td>
<td>65</td>
<td>65</td>
<td>Male</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>35</td>
<td>35</td>
<td>Female</td>
</tr>
</tbody>
</table>

Table 2: Distribution of cases according to Prakriti

<table>
<thead>
<tr>
<th>Prakriti</th>
<th>Group A No. of Patients</th>
<th>Percentage</th>
<th>Group B No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vataj</td>
<td>4</td>
<td>4%</td>
<td>03</td>
<td>03%</td>
</tr>
<tr>
<td>Pittaj</td>
<td>5</td>
<td>5%</td>
<td>04</td>
<td>4%</td>
</tr>
<tr>
<td>Kaphaj</td>
<td>1</td>
<td>1%</td>
<td>2</td>
<td>2%</td>
</tr>
<tr>
<td>Vatapittaj</td>
<td>20</td>
<td>20%</td>
<td>22</td>
<td>22%</td>
</tr>
<tr>
<td>Vatakaphaj</td>
<td>49</td>
<td>49%</td>
<td>50</td>
<td>50%</td>
</tr>
<tr>
<td>Pittakaphaj</td>
<td>13</td>
<td>13%</td>
<td>16</td>
<td>16%</td>
</tr>
<tr>
<td>Sannipataj</td>
<td>8</td>
<td>8%</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100%</td>
<td>100</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 3: Distribution of cases according to nature of work

<table>
<thead>
<tr>
<th>Nature of work</th>
<th>Group A No. of Patients</th>
<th>Percentage</th>
<th>Group B No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedentary</td>
<td>64</td>
<td>64%</td>
<td>61</td>
<td>61%</td>
</tr>
<tr>
<td>Active</td>
<td>36</td>
<td>36%</td>
<td>39</td>
<td>39%</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100%</td>
<td>100</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 4: Distribution of cases according to dietary habits

<table>
<thead>
<tr>
<th>Diet</th>
<th>Group A No. of Patients</th>
<th>Percentage</th>
<th>Group B No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vegetarian</td>
<td>42</td>
<td>42%</td>
<td>44</td>
<td>44%</td>
</tr>
<tr>
<td>Non-Vegetarian</td>
<td>58</td>
<td>58%</td>
<td>56</td>
<td>56%</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100%</td>
<td>100</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 5: Distribution of cases according to duration of disease

<table>
<thead>
<tr>
<th>Duration</th>
<th>Group A No. of Patients</th>
<th>Percentage</th>
<th>Group B No. of Patients</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>6months</td>
<td>68</td>
<td>68%</td>
<td>72</td>
<td>72%</td>
</tr>
<tr>
<td>01Yrs</td>
<td>22</td>
<td>22%</td>
<td>19</td>
<td>19%</td>
</tr>
<tr>
<td>Above1Yrs</td>
<td>10</td>
<td>10%</td>
<td>9</td>
<td>9%</td>
</tr>
<tr>
<td>Total</td>
<td>100</td>
<td>100%</td>
<td>100</td>
<td>100%</td>
</tr>
</tbody>
</table>

Clinical data
Table 6: Distribution of cases according to the symptoms before treatment and their relief after treatment in Group A

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>Nil</th>
<th>% of the pts relieved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td></td>
</tr>
<tr>
<td>Frequency of micturition</td>
<td>30 2</td>
<td>46 12</td>
<td>15 20</td>
<td>9 66</td>
<td>62.63</td>
</tr>
<tr>
<td>Dysuria</td>
<td>15 1</td>
<td>40 4</td>
<td>28 6</td>
<td>17 89</td>
<td>86.74</td>
</tr>
<tr>
<td>Haematuria</td>
<td>5 0</td>
<td>12 1</td>
<td>13 3</td>
<td>70 96</td>
<td>86.66</td>
</tr>
<tr>
<td>Intermittent Colicky pain</td>
<td>50 0</td>
<td>49 0</td>
<td>1 9</td>
<td>0 91</td>
<td>91</td>
</tr>
</tbody>
</table>

Table 7: Distribution of cases according to the symptoms before treatment and their relief after treatment in Group B

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Severe</th>
<th>Moderate</th>
<th>Mild</th>
<th>Nil</th>
<th>% of the pts relieved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td></td>
</tr>
<tr>
<td>Frequency of micturition</td>
<td>30 26</td>
<td>46 48</td>
<td>15 13</td>
<td>9 13</td>
<td></td>
</tr>
<tr>
<td>Dysuria</td>
<td>15 14</td>
<td>40 38</td>
<td>28 29</td>
<td>17 19</td>
<td></td>
</tr>
<tr>
<td>Haematuria</td>
<td>10 9</td>
<td>5 6</td>
<td>15 13</td>
<td>70 72</td>
<td></td>
</tr>
<tr>
<td>Colicky pain</td>
<td>42 41</td>
<td>22 20</td>
<td>34 37</td>
<td>2 2</td>
<td></td>
</tr>
</tbody>
</table>

Table 8: Distribution of cases according to size of Renal Calculi before treatment and their relief after treatment

<table>
<thead>
<tr>
<th>Size of calculi in mm</th>
<th>Group A</th>
<th>Group B</th>
<th>% of the pts relieved</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT AT</td>
<td>Nil</td>
<td>BT AT</td>
</tr>
<tr>
<td>4-6mm</td>
<td>41 2</td>
<td>39</td>
<td>95.12</td>
</tr>
<tr>
<td>7-10mm</td>
<td>59 9</td>
<td>50</td>
<td>84.74</td>
</tr>
<tr>
<td>Total</td>
<td>100 11</td>
<td>89</td>
<td>100 100</td>
</tr>
</tbody>
</table>

Table 9: Distribution of cases according to laboratory parameters in Group A

<table>
<thead>
<tr>
<th>Laboratory parameters</th>
<th>Nil</th>
<th>Up to 5</th>
<th>6-10</th>
<th>11-20</th>
<th>21-30</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
</tr>
<tr>
<td>Pus cells</td>
<td>0 0</td>
<td>59 86</td>
<td>31 14</td>
<td>10 0</td>
<td>0 0</td>
</tr>
<tr>
<td>Epithelial cells</td>
<td>0 0</td>
<td>4 98</td>
<td>78 2</td>
<td>16 0</td>
<td>2 0</td>
</tr>
<tr>
<td>Calcium Oxalates</td>
<td>0 0</td>
<td>86 91</td>
<td>10 7</td>
<td>4 2</td>
<td>0 0</td>
</tr>
<tr>
<td>RBCs</td>
<td>58 82</td>
<td>24 18</td>
<td>10 0</td>
<td>0 0</td>
<td>0 0</td>
</tr>
</tbody>
</table>

Table 10: Distribution of cases according to laboratory parameters in Group B

<table>
<thead>
<tr>
<th>Laboratory parameters</th>
<th>Nil</th>
<th>Up to 5</th>
<th>6-10</th>
<th>11-20</th>
<th>21-30</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
<td>BT AT</td>
</tr>
<tr>
<td>Pus cells</td>
<td>0 0</td>
<td>12 15</td>
<td>54 52</td>
<td>30 30</td>
<td>4 3</td>
</tr>
<tr>
<td>Epithelial cells</td>
<td>0 0</td>
<td>6 6</td>
<td>80 90</td>
<td>12 3</td>
<td>2 1</td>
</tr>
<tr>
<td>Calcium Oxalates</td>
<td>0 0</td>
<td>2 6</td>
<td>60 58</td>
<td>24 22</td>
<td>14 14</td>
</tr>
<tr>
<td>RBCs</td>
<td>64 70</td>
<td>28 26</td>
<td>8 4</td>
<td>0 0</td>
<td>0 0</td>
</tr>
</tbody>
</table>

Observations and Results
In this clinical study the following observations were noted
In the age group 31-40 maximum number of males were seen compared to females in both the Groups A and B (Table 1).
In Group A the maximum subjects were with vatakaphaj prakriti (49) followed by vatapitta pakriti (20). In Group B it was 50 and 22 respectively (Table 2).
The patients with sedentary life style were more prone to this disease than active subjects in both the Groups (Table 3).
The non-vegetarian were observed as 60 percent whereas vegetarian were 40 percent (Table 4).
It was observed that the patients with less duration were more than with that of longer duration in both the Groups (Table 5).
In Group A the symptoms of frequency of micturition, dysuria, haematuria and intermittent colicky pain before treatment were complained by 91,83,30,100 subjects respectively. After treatment complete relief was seen in 57, 72, 26, and 91 patients while the percentage is 62.63, 86.74, 86.66 and 91 in the above symptoms respectively (Table 6).
In the laboratory parameters pus cells, epithelial cells, Calcium Oxalates from 6-10 and beyond was seen in 41, 32, 14 and 10 subjects respectively and complete relief was observed in 27, 10, 5 and 24 while the percentage is 65.85, 31.25 and 35.75 respectively. In case of RBCs 34 patients were from 1-5 and above before treatment whereas 24 were completely relieved and the percentage of the same is 70.58.
Before the treatment, it was observed that 41 cases had a size 4-6 mm and 59 cases had a size of 7-10 mm in Group A. Complete relief was observed in 39 and 50 subjects while the percentage is 95.12 and 84.74 respectively in above sizes. In Group B 38 were falling in the size 4-6 mm and 62 in the size of 7-10 mm, there was no relief in this Group (Table 8).

**DISCUSSION**
On analysing the data it is evident that males are more prone to the disease as compared to females as the maximum subjects were males. The study suggests that the persons with vatakaphaj prakriti followed by vatapittaj prakriti are more prone to as the maximum number of subjects was having these prakritis. The study hints that the sedentary life style and non-vegetarian diets can cause the disease.
In this study, 62.63, 86.74, 86.66 and 91 percent of the subjects were completely relieved of frequency of micturition, dysuria, haematuria and intermittent colicky pain of Group A. It supports the Pramehahara, Mutrakricchrahara, Vata pitta samaka and Asmarihara properties of Gokshura.4
In the laboratory parameters 65.85 and 70.58 percent of the subjects were found with normal pus cell count and RBCs in Urine. After treatment in Group A. It supports the Vastisodhaka and Vata pitta samaka properties of Gokshura.
In this study, 95.12 and 84.74 percent of the subjects of Group A were found with absence of calculi through radiological investigation after treatment with sizes 4-6 mm and 7-10 mm before treatment respectively. It strongly supports the Asmarihara property of Gokshura.
Various other studies also support the above properties of the drug. Gokshura inhibits the growth of urinary calcium hydrogen phosphate dehydrate crystals. Gokshura is a diuretic drug useful in dysuria, renal dysfunction and renal calculus.5 The aqueous extract of Tribulusterrestris, in oral dose of 5gm/kg elicited a positive diuresis, which was slightly more than that.
of frusemide. In addition to its diuretic activity T. terrestris had evoked a contractile activity on Guinea pig ileum. The positive diuresis and contractile activity of may aid in the expulsion of renal calculus.

In Group B, there was no considerable relief in either the symptoms or in the expulsion of stone. No adverse drug reactions were observed during or after the study.

**CONCLUSION**

In this study, the demographic data supports that males are more prone to the disease. The persons with vatakaphaj prakriti and vata pitta prakriti are affected more. Sedentary life style and non-vegetarian diet may favour the occurrence of this disease.

In the aspect of clinical data the percentage relief in the symptoms and pass out of the stone did not reflect the percentage relief in the laboratory parameters in Group A. whereas in Group B there was no considerable change.

Hence it can be concluded that the Gokshura extract capsules were effective and safe in the cure of renal calculus as compared with the glucose powder capsules.

**REFERENCES**

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