A Pilot Study Evaluating Therapeutic Efficacy of Siddha Formulation ‘Nandukkal Parpam’ in the Management of Renal...

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PRECLINICAL AND CLINICAL STUDY ON GARPA VAAYU AND THE DRUG OF CHOICE IS SOOTHAGA VAAYU LEGHIUM AND VEEZHI ENNEI  View project
A Pilot Study Evaluating Therapeutic Efficacy of Siddha Formulation ‘Nandukkal Parpam’ in the Management of Renal Calculi

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Abstract: Objective: The present pilot study was designed to evaluate the effect of Nandukkal parpam (Calx of Fossil stone crab) a Traditional Siddha medicine in Kalladaippu (Urolithiasis) patients. Method: This study was conducted at the National Institute of Siddha, Tambaram, Chennai, India. The investigator recruited 10 patients with an inclusion and exclusion criteria. The patients were treated with 260 mg of Nandukkal parpam along with 50 ml Sirupeelai kudineer (freshly prepared decoction of the whole plant of Aerva lanata – Mountain Knot grass) twice a day for a period of 60 days. All the patients were taken laboratory investigations and Ultra Sono Gram (USG-KUB). Results: Normal sonographic study was observed in 6 patients and reduction in number of stones and stone size in 4 patients. There were no adverse events reported during the study and no recurrences during the follow up period of up to one year were reported. Conclusion: Results suggest that the trial drug Nandukkal parpam is effective and safe for the management of Kalladaippu (Urolithiasis) and in alleviating recurrences.

Keywords: Kalladaippu, Life style disorders, Nandukkal parpam, Siddha medicine, Urolithiasis.

1. INTRODUCTION

Today a large population suffers from kidney stone, gall stone and urinary calculi. Stone disease has gained increasing significance due to changes in life style and living conditions. Urolithiasis is the most common urological condition, accounting for significant morbidity; however adequate education regarding simple lifestyle modifications and early recognition of symptoms can reduce recurrence and visits to emergency department [1]. There is a strong evidence that diminished fluid and calcium consumption are risk factors [2-5]. Increased oxalate consumption has also been demonstrated to promote stone formation [6, 7]. Epidemiologic studies have demonstrated that increased sodium and animal protein intake has an equivocal impact on stone risk. Global climate change is another environmental factor that affects stone disease rates. Studies have documented the association between increased environmental temperatures and increased kidney stone rates [8]. Epidemiologic studies in the United States have shown that regions with higher average temperatures have the highest stone rates [9, 10].

Modern medications and surgical techniques used for the management and treatment of urolithiasis exhibit many complications [11]. Despite recent advances in the treatment of urolithiasis, it still continues to be a significant burden on a nation’s health care system. Hence, Modern medical science has set its quest with traditional medicines for its cost effective and safe medication. With increased quality of life along with life expectancy and lifestyle modifications, the utilization of Siddha medicine is gaining significance among the public day by day. Traditional Siddha formulations are time tested. Siddha system also aims in both the treatment and prevention of the disease. Nandukkal parpam (AYUSH approved formulary
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medication) is a widely used drug in Siddha system of medicine mainly as a diuretic and lithotriptic. In the present study, the Siddha formulation Nandukkal parpam was evaluated for its efficacy and safety in kalladaippu (urolithiasis) patients in a scientific manner.

2. METHOD

This pilot study was conducted in Ayothidoss Pandithar Hospital OPD.NO:1 Dept of Maruthuvam (Medicine), National Institute of Siddha, Tambaram sanatorium, Chennai-47 in accordance with standard protocol (NIS/PPHD/11/0105) after obtaining the approval of the Institutional Ethical Committee (IEC) (NIS/IEC/11/2/03–23/06/2011). The trial has registered in Clinical Trial Registry India (CTRI/2013/12/004203) and also posted on International Clinical Trials Registry Platform search portal (WHO). Before enrollment into the study the informed consent was obtained from the patients.

2.1. Conduct of Trial

A total of 10 patients between 20 and 60 years of age with renal calculi detected on X-ray KUB or USG abdomen, History of Recurrence of renal stone, Stone size 5mm &> 5mm to 10mm and Urine routine which will show crystals in urine were treated with 260 mg of Nandukkal parpam along with 50 ml Sirupeelai kudineer (freshly prepared decoction of the whole plant of Aerva lanata – Mountain Knot grass) orally twice a day after food for a period of 60 days. At each visit (once in 15 days) the vital signs, and clinical assessment were recorded in the CRF and medicines were issued. The patients were asked to follow the following dietary regimen and lifestyle modifications during the treatment and follow-up period.

1) Drink at least 2 liters of water every day.

2) Increase intake of dietary fiber, and green leafy vegetables.

3) Increase intake of foods with a high magnesium: calcium ratio (barley, bran, corn, buckwheat, rye, soy, oats, brown rice, banana, lima beans, and potato).

4) Get exercise daily.

5) Avoid smoking.

6) Reduce intake of high oxalate containing foods (black tea, cocoa, spinach, betel leaves, rhubarb, parsley, cranberry, nuts).

7) Limit dairy products, especially milk fortified with vitamin D.

8) Avoid sugar, salt and salt substitutes.

9) Avoid antacids.

10) Eat less meat and poultry.

11) Processed meats, tinned soups, snack foods, condiments, stock cubes and sauces are better avoided, due to their increased sodium content.

12) Red meat, tinned fish, meat extracts and mussels are to be avoided, which are rich in purine, which in turn increases the uric acid concentration.

13) Avoid excessive intake of alcohol.

14) Avoid suppression of urination.

15) Better to have eight hours of sleep.

All the patients went through laboratory investigations and USG-KUB at the end of treatment.

2.2. Study Outcome

Study outcome was defined as no evidence of renal calculi in X-ray KUB and USG-KUB, reduction in number of stones and stone size, clinical improvement and prevention of recurrence of stone formation for at least 1 year.

3. RESULTS

The USG-KUB revealed that in 6 patients there were no evidence of calculi and in 4 patients the stone size and also the number of stones were reduced after the completion of the treatment. Clinical symptoms such as pain and or burning while passing urine, pain from loin to groin accompanied by nausea, vomiting and gaseous distension were relieved during the treatment. The elevated serum calcium level (10.6-12.8mg/dl) in 4 patients was reduced into (10.5-11.2mg/dl) and other laboratory values were within normal range in all patients. There were no adverse events reported during the study and no recurrences in 6 patients who were completely cured, during the follow up period of up to one year were reported.
### Table 1. Patient detail.

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Age</th>
<th>Sex</th>
<th>Stone Size</th>
<th>Stone Nos</th>
<th>Site</th>
<th>Obstruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>28</td>
<td>Male</td>
<td>4mm, 5mm</td>
<td>7</td>
<td>Right mid calyx Right upper calyx Right lower calyx Left mid calyx Left upper calyx</td>
<td>No obstruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3mm, 5mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>50</td>
<td>Female</td>
<td>5mm</td>
<td>1</td>
<td>Mid pole of Right kidney</td>
<td>Mild hydroureteronephrosis (Right)</td>
</tr>
<tr>
<td>3</td>
<td>49</td>
<td>Female</td>
<td>7.5mm, 4mm</td>
<td>2</td>
<td>Distal Ureter of Right kidney</td>
<td>Mild proximal hydroureteronephrosis (Right).</td>
</tr>
<tr>
<td>4</td>
<td>36</td>
<td>Female</td>
<td>5mm</td>
<td>2</td>
<td>Right kidney Left kidney</td>
<td>No obstruction</td>
</tr>
<tr>
<td>5</td>
<td>36</td>
<td>Female</td>
<td>5.2 mm</td>
<td>3</td>
<td>Right lower pole Left lower pole</td>
<td>No obstruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.5mm, 4mm</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6</td>
<td>32</td>
<td>Male</td>
<td>6mm</td>
<td>1</td>
<td>Right mid calyx</td>
<td>No obstruction</td>
</tr>
<tr>
<td>7</td>
<td>37</td>
<td>Female</td>
<td>7mm</td>
<td>1</td>
<td>Lower ureter (Right)</td>
<td>Mild hydroureteronephrosis (Right).</td>
</tr>
<tr>
<td>8</td>
<td>60</td>
<td>Male</td>
<td>6mm, 4mm</td>
<td>3</td>
<td>Right mid calyx Left lower calyx</td>
<td>No obstruction</td>
</tr>
<tr>
<td>9</td>
<td>28</td>
<td>Male</td>
<td>7mm, 3mm</td>
<td>3</td>
<td>Right mid pole Left lower pole</td>
<td>No obstruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>34</td>
<td>Female</td>
<td>6mm</td>
<td>1</td>
<td>Right upper calyx Right mid calyx Left lower calyx</td>
<td>No obstruction</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4mm</td>
<td></td>
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</tr>
</tbody>
</table>

### Table 2. Treatment outcome.

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Stone Size</th>
<th>Stone Nos</th>
<th>Site</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>3.7mm</td>
<td>2</td>
<td>Right mid calyx Left lower calyx</td>
<td>Reduction in stone size and number, No obstruction</td>
</tr>
<tr>
<td></td>
<td>2.6mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>No evidence of renal calculi.</td>
<td></td>
<td></td>
<td>No evidence of renal calculi, No obstruction</td>
</tr>
<tr>
<td>3</td>
<td>No evidence of renal calculi.</td>
<td></td>
<td></td>
<td>No evidence of renal calculi, No obstruction</td>
</tr>
<tr>
<td>4</td>
<td>No evidence of renal calculi.</td>
<td></td>
<td></td>
<td>No evidence of renal calculi, No obstruction</td>
</tr>
<tr>
<td>5</td>
<td>3 mm</td>
<td>2</td>
<td>Right lower pole Left lower pole</td>
<td>Reduction in stone size and number, No obstruction</td>
</tr>
<tr>
<td></td>
<td>2.6 mm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>No evidence of renal calculi.</td>
<td></td>
<td></td>
<td>No evidence of renal calculi, No obstruction</td>
</tr>
<tr>
<td>7</td>
<td>No evidence of renal calculi.</td>
<td></td>
<td></td>
<td>No evidence of renal calculi, No obstruction</td>
</tr>
<tr>
<td>8</td>
<td>A microolith</td>
<td>1</td>
<td>Right lower pole</td>
<td>Reduction in stone size and number, No obstruction</td>
</tr>
<tr>
<td>9</td>
<td>2.6mm</td>
<td>1</td>
<td>Right lower pole</td>
<td>Reduction in stone size and number, No obstruction</td>
</tr>
<tr>
<td>10</td>
<td>No evidence of renal calculi.</td>
<td></td>
<td></td>
<td>No evidence of renal calculi, No obstruction</td>
</tr>
</tbody>
</table>
4. DISCUSSION

Kidney stones are the major disorders prevailing all over the world. About 75% of kidney stones are composed of calcium oxalate crystals [12]. According to the National Health and Nutrition examination survey, as of 2012, 10.6% of men and 7.1% of women in the United States are affected by renal stone disease [13]. Diet plays an important role in the development of kidney stones, especially in patients who are predisposed to the condition. Changes in diet, lifestyle and obesity increase the incidence of nephrolithiasis. A diet high in sodium, fat, meat and sugar, low in fiber, vegetable protein and unrefined carbohydrates increases the risk of renal stone disease [14]. Curhan et al. found that the prevalence and incidence of calcium oxalate stone disease was directly associated with body mass index (BMI) [15]. Nowfar et al. reported that a significant positive correlation exists between obesity and nephrolithiasis for both genders; however, obese females were more likely to develop stones than obese males [16]. Obesity epidemics, aging demographics, dietary indiscretions, global warming, all likely play a role in stone disease [17]. About 50% of all recurrent stone formers have just one recurrence during lifetime [18, 19].

Due to the advancement of modern science, stones larger than 5mm or stones that fail to pass through are treated only by interventional procedures such as ESWL, URS and PNL. Modern medication and surgical techniques currently being used for the management of urolithiasis exhibit many adverse effects such as haemorrhage, haematuria, tubular necrosis and subsequent fibrosis of the kidney.

Siddha formulations described in traditional texts for the management of renal calculi are comparatively economical and also clinically effective. Nandukkal parpam a herbo mineral formulation made of fossil stone crab, limestone, fullers earth, raddish juice and aerva lanata. Arunai nambiraj et al. tested the effect of oral administration of Nandukkal parpam on calcium oxalate microlithiasis in male wistar rats. The deposition of calcium oxalate crystals in kidneys of wistar rats on ethylene glycol and treated with Nandukkal parpam is much lesser than in the group of rats on ethylene glycol only (p<0.001) [20]. Administration of Aerva lanata aqueous suspension ((2g/kg body wt/day for 28 days) to CaOxurolithic rats had reduced the oxalate synthesizing enzymes and diminished the markers of crystal deposition in the kidney [21].

5. CONCLUSION

The Results of this pilot study strongly suggest that Nandukkal parpam may be very effective and safe in the treatment and management of Kalladaippu (Urolithiasis).

LIST OF ABBREVIATIONS

AYUSH = Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy
CaOx = Calcium oxalate
CTRI = Clinical Trial Registry India
ESWL = Extracorporeal shock wave lithotripsy
IEC = Institutional Ethics Committee
NIS = National Institute of Siddha
OPD = Out Patien Department
PNL = Percutaneous Nephrolithotomy
URS = Ureteroscopy
USG-KUB = Ultrasonography of Kidney, Ureter and Bladder
WHO = World Health Organization

CONFLICT OF INTEREST

The author(s) confirm that this article content has no conflict of interest.

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Declared none.

REFERENCES


