Clinical Trial on Renalka Syrup in Urinary Tract Infection

Garg, S.K.
Diplomat of National Board, Consultant Urologist, Heritage Hospital, Varanasi, India.

(Correspondence to: Mitra, S.K., Executive Director, Research and Technical Services, The Himalaya Drug Company, Makali, Bangalore, India.)

ABSTRACT
Urinary tract infection is the most common hospital acquired infection. Females are more prone to being infected. Various antibiotics have been used to treat this infection but they are not devoid of side effects. Renalka syrup, a herbal preparation (manufactured by The Himalaya Drug Company, Bangalore), was used in an open clinical trial conducted at Heritage Hospital, Varanasi, to substantiate its use as a safe and effective remedy in treating urinary tract infection. This trial has shown that 83% of patients with cystitis and 80% of patients with chronic prostatitis responded well to the drug without any significant side effects. (The Ind. Pract. 2000; (53(2): 133-135).

Key words: Urinary tract infection; cystitis; prostatitis; Renalka syrup.

INTRODUCTION
The most common site of hospital-acquired infections is the urinary tract, where approximately 40% of this type of infection occurs\(^1\). Females are more prone to develop urinary tract infection (UTI), especially lower UTI. Survey screening for bacteriuria has shown 1% incidence in school girls aged 5 to 14 years\(^2\), 4% by pre-adulthood and subsequently 1-2% as per decade of age. In addition, as a woman increases in age, she becomes increasingly prone to reinfection\(^3\). Various antimicrobials have been used for the prophylaxis and treatment of UTI but infection recurs in about half the number of patients within a few weeks after treatment. This result usually from either persistence of the organism in the urine during therapy, or by entry of new organisms into the bladder from the faecal-perineal reservoir and tends to occur unpredictably, although for reasons not understood, they occasionally cluster in time.

With the above limitations of existing antimicrobial treatment in mind, an open trial was conducted with a herbomineral product called Renalka syrup, the aim of the study being to evaluate its efficacy in the treatment of chronic urinary tract infection. The product’s main ingredients are *Tribulus terrestris*\(^4\)\(^\text{-}^6\), *Cretaea mangna*\(^7\)\(^\text{-}^8\), *Hemidesmus indicus*\(^9\), *Cyperus rotundus*\(^10\), *Vetiveria zizanioides*\(^11\), *Asparagus racemous*\(^12\) and *Elettaria cardamomum*\(^13\). The safety of this product was confirmed through experimental and clinical studies.

PATIENTS AND METHODS
The objective of the study was to evaluate the efficacy of Renalka syrup in patients of UTI. With this in view, an open clinical trial was conducted at Heritage Hospital, Varanasi. Fifty patients (23 males and 27 females) in the age group 17-65 years with a history of burning micturition, increased frequency of urination, fever, haematuria and pyuria were enrolled in the study. The diagnosis of UTI was based on clinical features and examination. Written informed consent was obtained from each patient.
Each patient in the study group was administered Renalka syrup at a dose of 2 teaspoonfuls twice a day for 2-4 weeks. They were followed up at regular intervals to evaluate the effect of the drug and to rule out any side effects. The response to the drug (Renalka syrup) was observed by urine examination and culture, total leucocyte count and differential count. The patients were divided into the following groups, as shown in Table 1.

**RESULTS**

All the patients who presented with symptoms of UTI were investigated before being included in the clinical trial group. Table 2 shows the response to Renalka syrup in UTI.

<table>
<thead>
<tr>
<th>Symptom</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystitis</td>
<td>36</td>
</tr>
<tr>
<td>Prostatitis</td>
<td>10</td>
</tr>
<tr>
<td>Prostatic abscess</td>
<td>1</td>
</tr>
<tr>
<td>Pyelonephritis</td>
<td>3</td>
</tr>
</tbody>
</table>

Of the 36 patients diagnosed with cystitis, 18 patients (50%) showed improved within a week, 10 patients (28%) responded well after 2 weeks of treatment and 2 patients (5%) showed response after 3 weeks of treatment. However, only 6 patients (17%) required adjuvant oral antibiotics before they responded.

In the group of 10 patients with prostatitis, 2 patients (20%) were asymptomatic after 2 weeks of treatment with Renalka syrup. However, 6 patients (60%) took 4 weeks to become asymptomatic and another 2 patients (67%) required injectable antibiotics to effect a cure.

At the end of the trial, none of the patients reported any significant side effects.

**DISCUSSION**

Treatment in the early stages of UTI has shown good results, but if left untreated, can lead to several complications. Various antibiotics have proved effective in treatment as well as in prophylaxis, e.g. trimethoprim, trimethoprim + sulphamethoxazole, nitrofurantoin, nitrofurantoin, fluoroquinolones and cephalosporins. However, there are several drawbacks encountered with antibiotic regimens and as a result, the organism persists in the urinary tract. This usually results from selection of an antimicrobial agent to which the organism is resistant and occurs especially with sulphonamide and ampicillin, particularly if these drugs have been used to treat previous infections. Sometimes, the patient fails to adhere to the prescribed medication routine and there are chances of poor compliance caused by nausea, epigastric distress or inadequate excretion of the drug in the urine.

In this trial, it was found that Renalka syrup was very effective in patients suffering from uncomplicated cystitis. Thirty patients (83%) with cystitis, responded well after treatment, 50% within the first week and 28% within 2 weeks and 5% within 4 weeks, which reveals excellent results. In those cases of chronic prostatitis, 80% of the patients were cured within 4 weeks of treatment. However, in pyelonephritis, only
33% of the patients showed improvement. These results compare favourably with those of fluoroquinolones used to treat cystitis and chronic prostatitis.

**CONCLUSION**

Considering the excellent results of the clinical trial, it can be concluded that Renalka syrup is effective in the treatment of cystitis and chronic prostatitis, without producing any undesirable side effects. In cases of chronic urinary tract infections, it may be useful if used for long term prophylaxis. However, a larger clinical trial is proposed to evaluate its efficacy in a wider perspective.

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