Role of Combination of Multiple Herbal Drugs (Septilin) in the Prophylaxis of Diabetic Foot Ulcer – A Double Blind Trial

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ABSTRACT
Infections, ischaemia and neuropathy are the major threats to diabetic foot apart from aerobic Gram-negative organisms, anaerobic bacteria such as bacteroides species play an important role in causing the infection. Septilin, a polyherbal formulation with various constituents having antimicrobial, anti-inflammatory and immunomodulatory properties was evaluated in patients with diabetic foot ulcers. Septilin was administered at a dose of 2 tablets twice daily for 12 weeks.

After 12 weeks of treatment, about 75% of the patients in Group A had sterile wound swab culture and 24% had some growth of E. coli and Proteus. There was no growth of Klebsiella in this group. In Group B, about 50% had recurrence of Gram-negative infection and about 28% of patients showed Gram-positive isolate in addition to Gram-negative culture. Two patients in Group B were dropped from the study, due to high blood sugar levels.

Key words: Diabetes; foot ulcers; Septilin; diabetic wounds

INTRODUCTION
Prevention and care of diabetic complications of the foot continue to present a major challenge to the physician. Besides infections, there are common, serious problems in diabetic patients. Neuropathy, infection, deformity and ischaemia are major threats to the diabetic foot and affect the functional well being of the diabetic patient. Of the total diabetic population, 20% of hospitalisation is due to foot problems, which require an average of about 22 days’ stay in the hospital. Apart from Staphylococci, Streptococci and enteric Gram-negative bacilli, anaerobic bacteria also play a significant role in producing infections and pose a threat to the healthcare system due to the exorbitant cost of treatment. Patients suffering from these ailments are faced with the insurmountable problems of delayed wound healing and recurrent infection.

Systemic antibiotics are useful in controlling infection but their role in the prophylaxis of wound infection does not outweigh the harmful effect of these drugs. Septilin, an Ayurvedic herbal formulation, is known for its antimicrobial and anti-inflammatory properties. It is used extensively as an immunomodulator and has also been employed in the treatment of various skin infections. With the above information in mind, a double blind trial was conducted to evaluate its efficacy in the prophylaxis of diabetic foot infections.

MATERIAL AND METHODS
Forty patients (30 males and 10 females) with diabetic foot, having peripheral neuropathy predominantly responsible for foot ulcer, were included in the study. After control of
hyperglycaemia and infection either with insulin or oral hypoglycaemics and initial treatment with appropriate systemic antibiotics, the patients were administered 2 tablets twice daily of either Septilin or an identical looking placebo for 12 weeks. The wound swabs were taken initially, at the end of 6 weeks and after 12 weeks of treatment.

The patients were fully informed regarding the composition of the drug and its role in infection. A written consent was obtained from each patient. The untoward effects of the drug, if any, were specifically recorded, during follow-up.

RESULTS

At the end of the study, patients receiving either Septilin or placebo were identified and bracketed into Groups A and B, respectively. There were 24 patients in the Septilin-treated group and 16 patients in the placebo-treated group. Mean age in group A was 51.16 years and 56.42 years in group B. Mean duration of diabetes was 5.82 years in group A and 6.72 years in group B (Table 1). The mean fasting and postprandial blood sugar levels were 110 ± 8.5 mg/dl and 142 ± 12.5 mg/dl respectively in Group A and 106 ± 12 mg/dl and 135 ± 15.0 mg/dl respectively in Group B (Table 2).

### Table 1: Demography of Patients

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>Age (Mean ± SD years)</th>
<th>Duration of diabetes mellitus (Mean ± SD years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A (n=24)</td>
<td>51.16 ± 16.20</td>
<td>5.82 ± 3.20</td>
</tr>
<tr>
<td>Group B (n=16)</td>
<td>56.42 ± 18.30</td>
<td>6.72 ± 2.85</td>
</tr>
</tbody>
</table>

### Table 2: Wound Swab Isolate after 12 weeks of Septilin & Placebo Treatment

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>Sterile</th>
<th>Staphylococcus</th>
<th>E. coli</th>
<th>Proteus</th>
<th>Klebsiella</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug</td>
<td>24</td>
<td>18 (75.0%)</td>
<td>-</td>
<td>4 (16.6%)</td>
<td>2 (8.3%)</td>
</tr>
<tr>
<td>Placebo</td>
<td>14</td>
<td>5 (35.7%)</td>
<td>5 (35.7%)</td>
<td>2 (14.3%)</td>
<td>1 (7.1%)</td>
</tr>
</tbody>
</table>

After 12 weeks of treatment, about 67% of the patients in Group A had sterile wound swab culture and 24% had some growth of *E. coli* and *Proteus*. There was no growth of *Klebsiella* in this group. In Group B, about 50% had recurrence of Gram-negative infection and about 28% of patients showed Gram-positive isolate in addition to Gram-negative culture. Two patients in Group B were dropped from the study, due to high blood sugar levels.

DISCUSSION

The inflammatory response of the tissue that is impaired in diabetes is attributable to ischaemia, hyperglycaemia and insulin deficiency. Phagocytic activity of macrophages is also diminished due to hyperglycaemia. As a consequence of diminished host response to infection and persistence of portal of entry because of delayed wound healing, recurrence of foot ulcer infection increases the cost of treatment. Poor wound hygiene in our population accentuates the problem. Treatment of infection in diabetic foot lesions is a novel trend and of utmost importance. In the present study, Septilin was employed in the treatment of this ailment owing to its assured safety and efficacy. It proved effective in decreasing infection rate and virulent organisms (Gram-positive) were specifically prevented in diabetic wounds.

Septilin contains the following ingredients of plant origin – *Balsamodendron mukul*, Maharasnadi quath, *Tinospora cordifolia*, *Rubia cordifolia*, *Emblica officinalis*, *Moringa pterygosperma*, *Glycyrrhiza glabra* and Shankh bhasma. These ingredients are known to possess properties useful in the stimulation of phagocytosis. They also have antibacterial
action against Gram-positive and Gram-negative micro-organisms, stimulation of ACTH and antioxidant action due to the presence of ascorbic acid\textsuperscript{14-17}.

**CONCLUSION**

It is concluded that patients receiving Septilin as a prophylaxis for diabetic foot infection had a lower incidence of recurrence of infection and Gram-positive infection in particular, was controlled.

**REFERENCES**


