Amputation Prevention Initiative in South India

Positive impact of foot care education

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OBJECTIVE — To determine whether intensive treatment and education strategies for type 2 diabetic patients with high-risk diabetic foot disease helps in preventing foot amputations.

RESEARCH DESIGN AND METHODS — Participants included 4,872 consecutive type 2 diabetic patients (male-to-female ratio 3,422:1,450, mean (±SD) age 60.5 ± 8.8 years, mean duration of diabetes 13.7 ± 7.6 years) with high-risk diabetic foot disease. The patients were categorized as high-risk subjects according to the International Consensus on the Diabetic Foot. The three study groups were subjects with diabetes and neuropathy (group 1; n = 2,871), diabetic neuropathy with deformity (group 2; n = 235), and diabetic neuropathy with deformity and foot ulceration or peripheral vascular disease (group 3; n = 1,766). Neuropathy was diagnosed by biothesiometry. Peripheral vascular disease was diagnosed as an ankle brachial index <0.8. All the subjects were educated regarding diabetic foot disease and its complications and prevention. They were also instructed to visit the center if any sign of new lesions appeared.

RESULTS — Among the 1,259 group 3 subjects who came for follow-up, 718 (57%) strictly followed the advice given and 541 (43%) did not. Ulcers present during the recruitment had healed in 585 (82%) subjects who followed the advice, but in only 269 (50%) subjects who did not. A significantly larger proportion of subjects who did not follow the advice developed new problems (26%) and required surgical procedures (14%) compared with those who followed the advice (5 and 3%, respectively).

CONCLUSIONS — Strategies such as intensive management and foot care education are helpful in preventing newer problems and surgery in diabetic foot disease.

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Diabetes is one of the leading causes of severe morbidity and mortality. The number of people with diabetes in the world is expected to double between 2000 and 2030. The greatest absolute increases in the number of people with diabetes will be in India (1). Foot problems are important contributory factors to the high morbidity and mortality observed in diabetic patients, and the socioeconomic impact of foot disease is substantial. It has been estimated that up to 50% of all nontraumatic lower limb amputations are performed on diabetic patients (2).

In India, diabetic foot disease is exacerbated by sociocultural factors such as the prevalence of walking barefoot, lack of knowledge regarding diabetic foot complications, and the socioeconomic status of patients (3). Diabetic foot infection constitutes ~10% of diabetes-related hospital admissions (4). In a study from Southern India, it was found that patients without foot problems spent 9.3% of their total income towards treatment, whereas patients with foot problems had to spend up to 32.3% of their total income on treatment (5). This huge challenge imposed by diabetic foot problems calls for prevention and effective management at the initial stages of disease.

There are no studies from India eliciting the outcome of cost-effective intensive management of diabetic foot complications. In this study, we assessed the effectiveness of an intensive treatment regimen combined with patient education on the prevention of foot amputations in South-Indian type 2 diabetic subjects.

RESEARCH DESIGN AND METHODS — The subjects were selected from the foot clinic of the M.V. Hospital for Diabetes, a speciality clinic attended by diabetic patients of all socioeconomic strata. Type 2 diabetic patients with high-risk foot disease were selected. The patients were categorized as high-risk subjects according to the International Consensus on the Diabetic Foot criteria (6). Consecutive diabetic subjects satisfying the criteria were recruited during a 27-month period (September 2001 to December 2003).

The three study groups included subjects with diabetes and neuropathy (group 1; n = 2,871), diabetic neuropathy and deformity (group 2; n = 235), and diabetic neuropathy with deformity and foot ulceration or peripheral vascular disease (group 3; n = 1,766). Among the patients in group 3, 231 (13%) patients had peripheral vascular disease, but none of them received intervention for peripheral vascular disease since these patients were not present with critical leg ischemia as assessed by a vascular surgeon attending the clinic. Neuropathy was diagnosed by biothesiometry (7). A vibration per-
exception threshold >25 volts was considered as abnormal. Peripheral vascular disease was diagnosed as an ankle brachial index <0.8. Foot examination was done to determine the presence of active foot ulceration.

All the subjects were educated regarding diabetic foot disease and its complications. They were also educated regarding regular foot examination. All the patients recruited in the study were given individual counseling in the presence of their family members. They were shown pictures of patients with foot infection, ulcers, and amputation to stress upon them the agony of developing such complications. They were individually shown how to check for any minor foot injuries using a mirror. Pedicure techniques were also taught to all patients. Handouts in the regional language emphasizing the need for foot care were also provided. Family members were requested to support the patient in foot examination and care as appropriate.

Patients in group 1 were provided foot care education, assistance in the selection of proper fitting footwear, and routine follow-up to manage simple problems. Patients in groups 2 and 3 were provided with customized orthoses to reduce foot pressure and were followed at more frequent intervals. Patients with foot ulcerations were provided the highest priority of care. These patients were instructed to visit the center if any sign of a new lesion appeared. A new ulceration was defined as an ulceration at the same or different site of a previous ulcer.

All patients were followed for >18 months. During the follow-up visits, adherence to the protocol was assessed by direct questioning of the subjects regarding their daily practice of using footwear, foot examination, and foot care. All the patients were questioned by a team member who was blinded to the results of patient follow-up. Adherence was considered satisfactory if the subjects followed the advice for at least 5 days a week.

RESULTS — Among 4,872 patients recruited into the study, 3,245 (67%) were available for follow-up (group 1: 1,837 of 2,871 [64%]; group 2: 149 of 235 [63%]; group 3: 1,259 of 1,766 [71%]). The clinical characteristics of the study groups are shown in Table 1.

In group 1 and 2 patients who attended follow-up visits, 6 (0.3%) and 7 (4.7%) subjects, respectively, developed new problems such as an infection or ulcer. In group 3, 174 of the 1,259 (13.8%) subjects followed developed new problems and 98 (7.8%) underwent surgical procedures.

Among the 1,259 group 3 subjects who attended follow-up visits, 718 (57%) strictly followed the advice given for foot care. Ulcers present during the recruitment had healed in 585 of the 718 (82%) subjects who adhered to the advice, whereas complete healing of ulcers was reported in only 269 of the 541 (50%) subjects who did not adhere to the advice (Table 2).

A significantly larger proportion of nonadherent subjects developed newer problems (26%) and required surgical procedures (14%) when compared with those who followed the advice (3 and 3%, respectively; P < 0.0001).

CONCLUSIONS — In the present study, there was less frequent recurrence of ulcers and a faster healing process in subjects adhering to the foot care advice provided. Some subjects were lost to follow-up, possibly due to socioeconomic reasons and the remote location of some patients’ homes. The larger follow-up percentage in group 3 could be attributed to the presence of ulcers that needed surgical treatment. In this study, all the subjects in group 3 received intensive care by means of regular contact and reviewing advice on foot care and management.

A number of studies have shown the beneficial effects of foot care education. In a study by Barth et al. (8), it was found that patients who were in an intensive educational group showed greater reduction in the number of foot problems requiring treatment in comparison with patients in the conventional group. Another study reported that patients who received the intervention were less likely than control patients to have serious foot lesions (9).

In an amputation prevention study by Patout et al. (10) conducted in an African-American population, intensive management of foot ulceration resulted in a 79% decrease in the incidence of lower extremity amputation and an 87% lower incidence of foot operations. In a longitudinal study of Chippewa Indians (11), it was shown that management of foot problems was effective in reducing lower extremity amputation by 50%.

One of the major limitations of this study design was that it was not a randomized trial. Given the high risk for foot complications in Indian diabetic patients, we could not randomize patients into a control

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### Table 1—Baseline characteristics of the study groups

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
<th>Group 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>2,871</td>
<td>235</td>
<td>1,766</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>2,041/830</td>
<td>186/49</td>
<td>1,195/571</td>
</tr>
<tr>
<td>Mean age (years)</td>
<td>59.9 ± 8.9</td>
<td>62.7 ± 8.2*</td>
<td>58.8 ± 9.4**</td>
</tr>
<tr>
<td>Mean duration of diabetes (years)</td>
<td>13.5 ± 7.6</td>
<td>14.9 ± 7.1*</td>
<td>12.8 ± 8.0*</td>
</tr>
<tr>
<td>Mean HbA1c (%)</td>
<td>9.5 ± 1.9</td>
<td>10.1 ± 2.1*</td>
<td>10.0 ± 2.0*</td>
</tr>
</tbody>
</table>

Data are means ± SD. *P < 0.005 vs. group 1; †P < 0.005 vs. group 2.

### Table 2—Comparison of group 3 patients who attended follow-up visits and had good or poor adherence to treatment advice

<table>
<thead>
<tr>
<th></th>
<th>Adherent</th>
<th>Nonadherent</th>
<th>χ²</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>718</td>
<td>541</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>10.2 ± 3.4</td>
<td>9.4 ± 2.6</td>
<td></td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Follow-up</td>
<td>9.2 ± 2.1</td>
<td>10.3 ± 3.3</td>
<td></td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Subjects with healed ulcer</td>
<td>585 (82)</td>
<td>269 (50)</td>
<td>141.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Healing time (days)</td>
<td>48 ± 18</td>
<td>90 ± 27</td>
<td></td>
<td>&lt;0.0001*</td>
</tr>
<tr>
<td>Subjects with new problems</td>
<td>33 (5)</td>
<td>141 (26)</td>
<td>117.6</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Subjects with new surgery</td>
<td>23 (3)</td>
<td>75 (14)</td>
<td>47.4</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Data are means ± SD or n (%). *P values determined by t test.
group; hence, all patients were provided with similar advice and intervention.

In this study, we provided simple foot care management advice to patients, such as daily examination of feet, how to perform a pedicure, and usage of proper footwear. Simple measures such as these may help in reducing foot complications, thereby preventing severe morbidity, and health care costs, particularly in developing countries. Through the proper education of the patients, it is possible to improve foot care practices among diabetic subjects. This conclusion needs to be confirmed by a planned, randomized, prospective study.

References