

PRESCRIPTION OF BIOMECHANICALLY APPROPRIATE FOOT ORTHOSES FOR ULCER FREE SURVIVAL IN TYPE 2 DIABETIC PATIENTS

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INTRODUCTION

The high rates of type 2 diabetes and its complications pose a major problem throughout the world. Foot infection, due to the presence of neuropathy and peripheral vascular disease [1] is a common complication of diabetes and is a leading cause for hospital admission among diabetic patients. Careful management of diabetic foot complications are essential to ensure the best outcome. It is necessary to consider patient-related measures such as survival, ulcer-free status and duration of ulcer-free survival. Ulcer free survival is an entity to measure the effectiveness of management of patients with foot ulceration. There are reports on the survival of diabetic amputees [2] but only few reports are available on the survival of diabetic patients with foot ulceration. The aim of this study was to assess the ulcer related outcomes and ulcer free survival in Indian type 2 diabetic patients with foot ulceration due to intervention by biomechanically soundly devised foot orthoses over a long term period.

METHODS

Consecutive type 2 diabetic neuropathic subjects with foot ulceration seen during a period of 48 months were selected for this analysis. High risk subjects according to international consensus on diabetic foot with foot ulcers (n=1143, M : F-756:387) were used to assess the ulcer free survival and ulcer related outcomes. Outcomes were determined after a minimum follow up of 3 months. HbA1c% was estimated by immunoturbidimetric method. Neuropathy was diagnosed by vibration perception threshold. Peripheral vascular disease was diagnosed if the ankle brachial pressure index (ABI) was <0.8. Ulcer outcomes were defined as healed, unhealed, major or minor amputation and death. Healing was defined as complete epithelialization without discharge. Ulcers were managed by pressure offloading through specially designed foot orthoses, treatment of infection and podiatric care. Different kinds of insoles were used to develop therapeutic foot wear for the patients with foot ulcers.

STATISTICAL ANALYSIS

Descriptive statistics were computed with means and SD for continuous measurements. Median and range are reported and group comparisons were done by chi-square test, student's 't' test as relevant. Kaplan-Meier technique was used for survival analysis. Gender wise differences in

survival analysis was done by Taron-Wale statistics. P<0.05 was considered as statistically significant.

RESULTS

Analysis of the Ulcer related outcomes among the study subjects shows that out of 1143 subjects, a total of 876 (76.6%) ulcers healed, but only 704 (61.6%) of ulcers healed and remained ulcer free by the end of the follow up period. About 267 (23.4%) ulcers never healed and in 172 (15.1%) ulcers healed and recurrence of ulcer was seen. Of the ulcers, 15

resulted in an amputation and 5 of the patients died.

Figure 1. shows the results of survival analysis. No gender wise difference (p > 0.05) was noted in the survival analysis. Table 1. shows the comparison between ulcer free patients and patients with recurrent ulcers. Intergroup differences are not seen for mean age and duration of diabetes. Usage of therapeutic footwear (24.4 Vs 63.4% p<0.0001) was lower among patients with recurrent ulcers when compared with ulcer free patients.

DISCUSSION:

Ulcer – free survival is a new concept of management of foot ulcers. Median time for the patients free from ulcer was 6 months over a period of 48 months. There was no gender wise significant difference in patients. In summary, the study showed that about 60% of ulcers healed and remained ulcer-free by the end of the follow up period. Recurrence of ulceration and number of amputations were less. This was achieved by providing education on foot care and appropriate protective foot wear to the patients. Burden of foot problems may be reduced by initiating simple preventive measures in developing countries.

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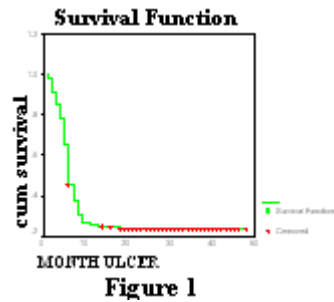


Figure 1

Table 1: Comparison between ulcer free and recurrent ulcer patients. {Values are mean (SD)}	Ulcer free patients	Recurrent ulcer patients	P value
Number	704	172	
Age (in years)	57.5 (9.0)	57.8 (8.9)	0.7
Duration of diabetes (in years)	11.9 (7.4)	12.5 (8.2)	0.4
Therapeutic foot wear	446 (63.4)	42 (24.4)	<0.0001