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Effectiveness of a new brand of stock 'diabetic' shoes to protect against diabetic foot ulcer relapse – a prospective cohort study.

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ABSTRACT

Aims

Diabetic patients with podopathy (diabetic foot syndrome) may need protective footwear, be it customised or industrially produced stock ‘diabetic’ shoes (SDS). The effectiveness of each type of ‘diabetic’ shoe needs to be proven clinically, e.g. in terms of prevention of foot ulceration. The following study assesses a new German SDS, the LucRo® shoe, which consists of rocker-shaped walking sole, a standardised shock absorption insole, and soft uppers without stiff toe-caps. The LucRo® SDS has been registered as a Medicinal Product according to the European Community Guideline 93/42/EC.

Patients and methods

A total of 92 high-risk diabetic patients (mean age 63 years, duration of diabetes 13 years) with healed foot ulcer were recruited prospectively over 31 months; 87 patients suffered from polyneuropathy, 24 patients had peripheral ischaemic vessel disease. One group of patients (n = 60) received the LucRo® SDS and wore them, whilst the remaining patients (n = 32) did not receive the SDS and were forced to use their normal footwear. This allocation reflects the haphazard reimbursement policies of the individual patients’ health insurance, and is in accordance with the current German legislation. The patients were followed up for up to 42 months until the first foot ulcer relapse, or the end of the study.

INTRODUCTION

Footwear significantly affects the course of the diabetic foot syndrome (diabetic podopathy). If unsuitable, footwear injures the feet, thereby increasing the risk of amputation in patients with loss of protective sensation. If appropriate, footwear can protect the feet from such lesions. Mismatch between foot and shoe, and ‘normal’ shoe design or materials are casually involved in nearly 80% of all foot lesions that precede amputations in diabetic patients [1]. Empirical criteria for the making of special ‘diabetic’ protective footwear were devised some time ago [2]. However, intervention studies with diabetic footwear are rare,

and proof of its efficacy in terms of clinical endpoints, e.g. prevention of foot ulceration, is still scarce [3]. Clinical trials of ‘diabetic’ footwear in free-living patients are difficult to perform: some patients would reject them for cosmetic reasons, while others would wear them only temporarily [4,5]. However, one of the main problems is the lack of standardisation of both ‘diabetic’ footwear and diabetic feet regarding size and shape [6]. Previous reports have claimed clinical benefits for some stock ‘diabetic’ shoes, but there were limitations within the methodology utilised [5,7-9]. Since there is no unequivocal clinical proof of the effectiveness of ‘diabetic’

Results

There were no differences between the groups concerning age, sex, type and duration of diabetes, prevalence of polyneuropathy and peripheral ischaemic vessel disease, frequency of foot care and mortality rate. The first year annual rate of foot ulcer relapse was significantly different between the groups: 60% without SDS vs. 15% with SDS. The overall cumulative ulcer-free survival was significantly greater with SDS (P < 0.0001, log rank test).

Conclusion

The LucRo® stock ‘diabetic’ shoe appears effective in the prevention of foot re-ulceration in high-risk patients with diabetic podopathy.

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Keywords

Amputation, diabetic foot, diabetes, complications, foot ulcer, neuropathy, shoes, footwear.

Abbreviations

ICD-10 no., International Classification of Diseases, 10th Version (in German); SDS, stock ‘diabetic’ shoes; Euro, European currency (1 Euro is approximately £0.70, or US\$1); PIVD, peripheral ischaemic vessel disease; PNP, polyneuropathy.

stock shoes, the German health insurance companies generally do not cover the costs of stock ‘diabetic’ shoe (SDS) prescription, whereas they are legally obliged to reimburse any kind of prescribed medication. However, on demand some of the approximately 500 various local, regional, and industry-based health insurances reimburse approximately 170 Euro for each pair of ‘diabetic’ stock shoes, which is about two-thirds of the total costs. It is not publicly known which insurances do or do not reimburse the costs of ‘diabetic’ stock shoes, and likewise, neither are reimbursement policies followed consistently over time.

Thus, the attitude of German health insurances is unpredictable and haphazard.

The rate of foot ulcers can be high (58-100% per year) in unprotected high-risk patients with a history of diabetic foot lesions [9,10]. Treatment with protective footwear can lower this rate considerably [3,9,11,12], which makes a randomised, placebo-controlled trial with an unprotected control group of high-risk patients problematic. The following study was therefore conducted with a cohort of health insurance beneficiaries, to whom their insurance companies – by chance – either provided or withheld stock ‘diabetic’ shoes.

PATIENTS AND METHODS

Study design

The study was a single-centre, prospective cohort study, using health insurance-based data, and practice registry and case notes. The study assessed the effects of a particular stock ‘diabetic’ shoe on the rate of foot ulcer relapses in patients with diabetic podopathy. Approval from the local ethics committee was obtained.

Patients

The patients included in the study all belonged to a large practice of two internists specialising in diabetology. The practice is located in an industrial city in Western Germany (approx. 600,000 inhabitants), with about 2,000 patients with diabetes.

The patients were selected from the practice’s patients registry according to the following criteria: beneficiaries of a state-approved or private health insurance, diabetes with complications [ICD-10 no. 10.7 (Type 1 diabetes) or ICD-10 no.11.7 (Type 2 diabetes)], and had received treatment for a foot ulcer [according to the practice’s application for reimbursement for wound care (general practitioners’ procedure numbers 2002, or 2004, or 2020, or 2021 wound care)]. The foot ulcer had to be healed completely by that practice (see below). The patients had to have polyneuropathy (PNP) and/or peripheral ischaemic vessel disease (PIVD); major foot deformations and limitations in mobility of foot joints had to be absent. A particular type of stock footwear (see below) had to be prescribed within 4 weeks after healing of the ulcer between June 1999 and June 2001; the patients had to remain attached to the practice until the end of the study on 31 December 2001.

A total of 92 patients met the inclusion criteria and were followed for ulcer relapses. These clinical characteristics are summarised in Table 1.

Definitions

PNP was diagnosed using the Rydel-Seiffer tuning fork [13]; a vibration sensation < 5/8 at the first metatarsal head indicated PNP.

PIVD was diagnosed using a continuous wave 8-mHz Doppler device; an ankle/arm pressure index < 1.0 or an abnormal flow profile suggestive of collateral circulation.

A foot ulcer was defined as any partial or complete disruption of the skin (Wagner stage 1-2), with or without inflammation. Healing of an ulcer was defined as complete closure of a lesion with durable skin, leading to the cessation of wound care.

Stock ‘diabetic’ shoes

The same brand of industrially made SDS was prescribed (LucRo®, Schein Orthopädie Service KG, Remscheid, Germany), which had basically the same design, but varied in colour and version for men and women. Other particular features of the LucRo® shoes were as follows: three widths (small, medium, large); stiff, convex walking sole (‘rocker bottom’) from ethylene-vinyl-acetate and rubber (Softgummi®); very soft upper of three layers (from inner to outer: cloth, rubberfoam, leather) without any kind of toe cap; a shock-absorbing standardised, non-moulded insole comprising three components (rear part 6 mm Lunasoft®, 42° Shore A hardness; anterior part 6 mm Lunaflex®, 20° Shore A hardness, covered with 3 mm thick PPT, 17° Shore A hardness). The outline of the anterior part of the insole is less triangular and more rectangular (Fig. 1), fitting reasonably to the dimensions of the feet of elderly persons [6], and corresponding to the shape devised by Helbig et al. on the basis of anthropometric measurements in healthy men [14].

TABLE 1 CLINICAL CHARACTERISTICS OF THE PATIENTS UNDER STUDY

	Withheld*	Provided*	P -value
Patients with SDS prescription, n	32	60	
Gender (M/W), n	18/14	31/29	NS
Age, years	67 (50,74)	62 (54,73)	NS
Known duration of diabetes, years	15 (6,23)	12 (5,15)	NS
Length of follow up, months†	5 (2,19)	19 (8,25)	< 0.05
Patients with:			
Type 1 diabetes, n (%)	3 (9%)	5 (8%)	NS
Type 2 diabetes, n (%)	29 (91%)	55 (92%)	NS
PNP, n (%)	29 (91%)	58 (97%)	NS
PIVD, n (%)	8 (25%)	15 (25%)	NS
Ulcer relapse, n (%)	25 (78%)	12 (20%)	< 0.001
Visits to the practice per patient per month, n	1.0 (0.6, 1.5)	0.8 (0.5, 1.2)	NS
Foot care sessions, per patient per month, n	0.6 (0.1, 0.7)	0.5 (0.1, 0.6)	NS
Patients deceased during follow up, n (%)	1 (3%)	4 (7%)	NS

* Due to withholding/providing reimbursement by individual patients’ insurance companies. Medians (interquartile range), or numbers (%), as indicated. NS, Not significant; PNP, polyneuropathy; PIVD, peripheral ischaemic vessel disease; SDS, stock ‘diabetic’ shoe.

† Until ulcer relapse, death, or end of study.



Fig. 1 Shape of the bottom of the stock ‘diabetic’ shoe under study, and the insole, respectively. Size 27.5cm French system. Bar indicates 5 cm distance.



Fig. 2 LucRo® shoe, women’s version. The upper is easily deformable by gently touching with a fingertip.

A picture of such an SDS is shown in Fig. 2. The softness of the upper, – which is easily deformable, see Fig. 2 – is required to avoid toe pressure strain. The rocker-bottom decreases peak plantar pressures beneath the metatarsal heads and prolongs pain-free walking distance in cases of PIVD [15], and the insole acts by cushioning the planta pedis in the forefoot area (where most pressure strain occurs during walking). These items [3] had been recommended by Tovey [2] on empirical grounds. Furthermore, the LucRo® shoe was designed based on earlier experiences with other brands of German SDS [5,8,11]. The LucRo® SDS has been registered as an approved medicinal product class 1, in conformity with the European Community Guideline 93/42 EC.

By contrast to these SDS, normal fashion shoes (e.g. Oxford style) mostly have only one width which is too narrow for most diabetic feet [6], have a (stiff) toe cap, and hard insoles [3].

Allocation of stock ‘diabetic’ shoes

At least one pair of SDS was prescribed, provided the foot shape was suitable for the SDS at the shoe fitting. The prescription was given to one single retailer (Innova-med Inc., Haan, Germany), who then by letter applied to the patients’

insurance companies for reimbursement. In all cases, he as well as the patients received response letters of either approval or decline by their insurances. While 15 insurances (including Allgemeine Ortskrankenkasse and various Betriebskrankenkassen) of 60 patients approved

reimbursement of approximately two-thirds of the total costs of approx. 250 Euro, four insurances (Deutsche Angestelltenkrankenkasse, Technikerkrankenkasse, Bundesknappschaft, Betriebskrankenkasse Hoesch) of 32 patients categorically declined to reimburse any part of the costs. Thus 60 patients received the SDS from the retailer while the latter 32 did not; this was confirmed by cross checking the data on file of the SDS retailer and the practice. If the patients were satisfied by the first pair of SDS, one or two more pairs were prescribed and the appropriate reimbursement received.

In conclusion, the present data indicate that one brand of stock ‘diabetic’ shoe, the LucRo® shoe, can reduce the incidence of foot ulcer relapses by 45% in the first year in high-risk diabetic patients with polyneuropathy and/or ischaemic vessel disease and a history of foot ulceration. Future trials are warranted to prove its efficacy in different patient populations.

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