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REVIEW ARTICLE

Patient education for preventing diabetic foot ulceration

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Summary

Treatment of diabetic foot ulceration is very challenging, costly and often needs to be of long duration. This leads to substantial economic burden. Population-based research suggests that a meaningful reduction of the incidence of amputations caused by diabetes mellitus has already been achieved since the St. Vincent resolution in 1989. Still, it cannot be inferred from these studies that the current preventive efforts are (cost-)effective because reduction of amputation incidence can also be the result of improvements in ulcer treatment. Nevertheless, education of people with diabetes is widely advocated and implemented in standard practice. Despite the fact that preventive interventions are often combined in daily practice, there is little scientific evidence demonstrating the effect of those efforts. In systematically reviewing the evidence, there is insufficient evidence that limited patient education alone is effective in achieving clinically relevant reductions in ulcer and amputation incidence. To date, high quality evidence that more complex interventions including patient education can prevent diabetic foot ulceration is not available either. This, however, should be interpreted as lack of evidence rather than evidence of no effect. Future directions for research and practice may be to concentrate preventive effort on those patients who appear to be at highest risk of foot ulceration after careful screening and selection.

Keywords diabetic foot; ulcer; patient education; complex intervention; prevention

Foot ulceration affects 15% to 25% of people with diabetes mellitus at some point during their life [1]. Even with immediate and intensive treatment, foot ulcers may take weeks or months to heal or may not heal at all. Moreover, 70% of foot ulcer patients have recurrent lesions within 5 years after treatment [2]. This not only leads to physical disability and marked reduction of quality of life but also precedes the majority of lower-extremity amputations [3–6]. Patients with neuropathic diabetic foot ulceration have a 7% risk of amputation in the next 10 years [7].

Treatment of diabetic foot ulcers is very challenging and often needs to be of long duration. Because expert interference, orthopaedic appliances, antimicrobial drugs, topical dressings and sometimes inpatient care are required, this results in substantial economic burden. Healthcare costs of a single ulcer are approximately $17 500 (1998 US dollars), or $30 000–33 000 in case of lower-extremity amputation [8–10]. When loss of productivity, preventive efforts, rehabilitation and home care are also taken into account, 7–20% of the total expenditure on diabetes in North America and Europe are attributable to foot ulceration [11].

In 1989, one of the 5-year targets of the European Declaration of St. Vincent was a 50% reduction in amputations caused by diabetes mellitus [12]. International guidelines underpinned this drive by outlining foot ulcer prevention strategies such as optimizing metabolic control, identification and screening of people at high risk for diabetic foot ulceration and patient education in order to promote foot self-care [13–15]. Teaching diabetes patients the principles of self-examination of the feet and foot care has since long been advocated as an essential attribute of prevention strategies and is widely implicated in clinical practice [16].

Recent population-based research suggests that nowadays a meaningful reduction of the incidence of amputations caused by diabetes mellitus has been achieved [17,18]. This, however, may be attributable to improvements in ulcer treatment and therefore does not necessarily support (cost-)effectiveness of preventive efforts.

The importance of patient education is outlined by several review articles [19–26]. Yet, only two of these are systematic reviews; most dealt primarily with uncontrolled studies, and only one assessed risk of bias. Hereby, we summarize the results of our systematic reviews, published in the Cochrane database of systematic reviews, of the effectiveness of education (alone or as part of a complex intervention) targeted at people with diabetes for the prevention of foot ulceration, on the basis of reports of the currently available randomized controlled trials (RCTs) [27,28].

Trials evaluating patient education

Eleven prospective RCTs which evaluated educational programmes for preventing foot ulcers in people with diabetes mellitus were identified after searching Ovid MEDLINE, Ovid EMBASE, EBSCO CINAHL, the Cochrane Wounds Group Specialized Register and the Cochrane Central Register of Controlled Trials on 22 December 2009 (Table 1). Three studies described the effect of foot care education as part of a general diabetes education programme compared with usual care [29–31]. Two studies examined the effect of a brief foot care education session tailored to educational needs compared with no intervention [32,33]. Finally, six studies described the effect of intensive compared with brief educational interventions [34–40].

Marked clinical heterogeneity precluded pooling of outcome data. Moreover, the effect of patient education on foot ulceration and amputations, the main outcomes of interest, was assessed in only four studies. Malone *et al*. reported a statistically significant benefit of 1-h group education for people with diabetes who were at high risk for foot ulceration after 1-year follow-up; relative risk (RR) amputation, 0.33 (95% CI 0.15 to 0.76); RR ulceration, 0.31 (95% CI 0.14 to 0.66) [38]. This study, however, was at high risk of bias and may have overestimated the effect because the outcomes were reported per limb instead of per patient. One similar but methodologically superior study, performed by Lincoln *et al*., did not confirm this finding. Although 71 foot ulcers and 18 amputations were observed during 1-year follow-up of diabetes patients at high risk for foot ulceration who received 1 h group education or written foot care instructions only, the incidence rates did not differ between groups; RR amputation, 0.98 (95% CI 0.41 to 2.34); RR ulceration, 1.00 (95% CI 0.70 to 1.44) [37]. Finally, in two studies published in three papers, too few events were observed to detect any effect of education on ulcer incidence or amputation [29,39,40].

Patients' foot care knowledge was improved in the short term in five of eight RCTs in which this outcome was assessed, as was patients' self-reported self-care behaviour in the short term in seven of nine RCTs. However, in the one study with longer follow-up, performed by Rönnemaa and colleagues, the difference in foot care knowledge and self-care behaviour between intervention and control group had disappeared at 7 years [39,40]. The effects on callus, nail problems and fungal infections were described in five of the included studies. Only two reported temporary improvements after an educational intervention.

Importantly, all but one of the included RCTs in this systematic review were at high or unclear risk of bias. This was mainly caused by insufficient reporting. Usually, methodological flaws, such as inadequate randomization, inadequate blinding, and selective follow-up, lead to overestimation of the effect size, especially when subjective outcome measures are reported, such as foot care knowledge and patient behaviour. Therefore, the few positive effects that were found should be interpreted with caution.

Trials evaluating complex interventions

In clinical practice, patient education is often combined with other preventive interventions. These interventions may, like patient education, aim to improve patients' health outcomes directly (patient-level intervention). Examples are podiatry care, foot ulceration risk assessment and motivational coaching to reinforce foot self-care behaviours. But interventions to prevent foot ulceration may also benefit patients indirectly through improving healthcare professionals' ability to provide adequate care (care provider level intervention) or through improving the healthcare system (structure of health care level intervention). Examples of the first are healthcare provider education, introduction of flow sheets for risk assessment and referral or introduction of new screening instruments for foot ulceration risk assessment. Examples of healthcare structural interventions in general may include the introduction of a multidisciplinary team approach or measures to improve regularity of follow-up and continuity of care [41,42].

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Table 1. Randomized controlled trials evaluating patient education for preventing diabetic foot ulceration

Study ID	Setting	Intervention	Participant number/ duration of follow-up	Main outcomes
Mazzuca *et al*. [30]	Primary care	General diabetes education versus usual care	532/1 year	Foot care knowledge: no difference
Rettig *et al*. [31]	Community-based care	General diabetes education versus usual care	471/6 months	Foot care knowledge: favours intervention Self-care behaviour: no difference Foot appearance: no difference
Bloomgarden *et al*. [29]	Primary care	General diabetes education versus usual care	345/1.5 years	Self-care behaviour: no difference Callus, nail dystrophy and fungal infection: no difference Foot ulceration/amputation: no difference
Malone *et al*. [38]	Secondary care	Intensive versus brief foot care education	203/1 year	Ulcer incidence: 0.31 (95% CI 0.14–0.66)[a] Amputation rate: 0.33 (95% CI 0.15–0.76)[a]
Barth *et al*. [34]	Secondary care	Intensive versus brief foot care education	70/6 months	Foot care knowledge: favours intensive Self-care behaviour: favours intensive Foot problems requiring treatment: no difference
Kruger *et al*. [36]	Secondary care	Intensive versus brief foot care education	50/6 months	Foot care knowledge: favours control Self-care behaviour: favours intervention on 2 out of 5 items
Hamalainen *et al*. [39]; Rönnemaa *et al*. [40]	Community-based care	Intensive versus brief foot care education	530/7 years	Foot care knowledge: no difference Self-care behaviour: no difference Presence of calcaneal callus: RR 0.96 (95% CI 0.55–1.70)[a] Presence of callus in other regions: RR 0.77 (95% CI 0.53–1.01)[a] Foot ulceration/amputation: no difference (2 vs 1)[a]
Frank [35]	Primary care	Intensive versus brief foot care education	100/4 weeks	Foot care knowledge: favours intervention Self-care behaviour: favours intervention on 1 out of 4 items
Corbett [32]	Community-based care	Brief foot care education tailored to individual needs versus no intervention	40/6 weeks	Foot care knowledge: favours intervention Self-care behaviour: favours intervention
Borges and Ostwald [33]	Emergency department	Brief foot care education tailored to individual needs versus no intervention	167/4 weeks	Foot care knowledge: favours control Self-care behaviour: favours intervention
Lincoln *et al*. [37]	Secondary care	Intensive versus brief foot care education	178/1 year	Self-care behaviour: favours intervention Ulcer incidence: RR 1.00 (95% CI 0.70–1.44)[a] Amputation rate: RR 0.98 (95% CI 0.41–2.34)[a]

[a]Intervention versus control.
RR, relative risk.

Five prospective RCTs that evaluated combinations of preventive strategies, not solely patient education, for preventing foot ulcers in people with diabetes mellitus were identified after searching Ovid MEDLINE, Ovid EMBASE, EBSCO CINAHL, the Cochrane Wounds Group Specialized Register and the Cochrane Central Register of Controlled Trials on 28 May 2010 (Table 2). The study characteristics were heterogeneous in terms of healthcare settings, the nature of the interventions studied and outcome measures reported.

In three studies that compared the effect of an education-centred complex intervention with usual care or written instructions only in diabetes patients at low or medium risk for foot ulceration, little evidence of benefit was found [39,40,43,44]. Two studies compared the effect of more intensive and comprehensive complex

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Table 2. Randomized controlled trials evaluating complex interventions for preventing diabetic foot ulceration

Study ID	Setting	Intervention	Participant number/ duration of follow-up	Main outcomes
Litzelman *et al*. [43]	Primary care	Patient education, self-care reinforcement and care provider education versus care as usual	396/1 year	Self-care behaviour: favours intervention Serious foot lesions: odds-ratio 0.41[a] Amputation: no difference (1 vs 4)[a]
Hamalainen *et al*. [39]; Rönnemaa *et al*. [40]	Community-based care	Patient education and podiatry care versus written foot care instructions only	530/7 years	Foot care knowledge: no difference Self-care behaviour: no difference Presence of calcaneal callus: RR 0.96 (95% CI 0.55–1.70)[a] Presence of callus in other regions: RR 0.77 (95% CI 0.53–1.01)[a] Foot ulceration/amputation: no difference (2 vs 1)[a]
McCabe *et al*. [45]; Klenerman *et al*. [49]	Secondary care	Intensified care and education for selected high-risk patients versus care as usual	2001/2 years	Foot ulceration: RR 0.69 (95% CI 0.41–1.14)[a] Amputation: RR 0.30 (95% CI 0.13–0.71)[a]
Donohoe *et al*. [44]	Primary care	Patient foot care education and care provider education versus patient education on nephropathy	1939/6 months	Foot care knowledge: improvement in both groups
McMurray *et al*. [46]; McMurray and McDougall [47]	Secondary care	Individualized care and education by a multidisciplinary team versus care as usual	83/1 year	Self-care behaviour: favours intervention Amputation: 0 vs 5[a]

[a]Intervention versus control.
RR, relative risk.

interventions with usual care in patients at high risk for foot ulceration [45–47]. McMurray *et al*. reported improvement of patients' self-care behaviour, but the study enrolled too few subjects to evaluate differences in amputation incidence rates [46,47]. In a study by McCabe *et al*., 2001 patients were randomized to receive a detailed foot ulceration risk assessment followed by intensified care for those at high risk, or care as usual [45]. The intensive intervention comprised more intensive follow-up, a weekly diabetic foot clinic, podiatry care, provision of support hosiery and protective footwear and introduction of appointment reminder letters to patients. A significant and cost-effective reduction of lower-extremity amputations (RR 0.30; 95% CI 0.13 to 0.71) was achieved and also a non-significant reduction of the number of foot ulcerations (RR 0.69; 95% CI 0.41 to 1.14).

Importantly, all five RCTs assessing the effect of complex interventions were at high risk of bias, with hardly any of the predefined risk of bias assessment criteria met.

Discussion

On the basis of the 11 RCTs that evaluated educational programmes for preventing foot ulcers, we conclude that there is insufficient robust evidence that limited patient education alone is effective in achieving clinically relevant reductions in ulcer and amputation incidence. Available studies are generally underpowered and at high or unclear risk of bias with the exception of the study by Lincoln *et al*., showing no benefit of more intensive versus brief foot care education [37]. Despite the fact that complex interventions for preventing diabetic foot ulceration are widely used in clinical practice worldwide, only five RCTs evaluating the effectiveness of these types of interventions were available. Therefore, we also conclude that there is insufficient evidence to support the effectiveness of complex interventions for preventing diabetic foot ulceration. This, however, should be interpreted as lack of evidence rather than evidence of no effect.

More well-designed and well-powered RCTs evaluating the effect of intensive comprehensive complex interventions are urgently needed. Although large trials are costly, the benefits in terms of reduction in costs associated with effective treatment are potentially significant. In current clinical practice, it may be advisable to concentrate preventive efforts on those who appear to be at high risk for foot ulceration after careful screening and selection [48]. Prevention programmes should not be limited to patient education only but should consist of multiple combined interventions.

Conflict of Interest

None declared.

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