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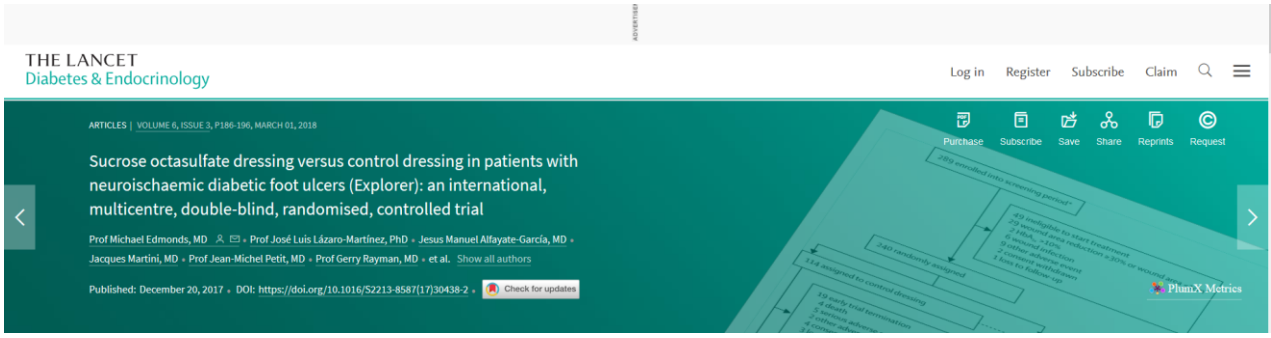

Summary

Background

Diabetic foot ulcers are serious and challenging wounds associated with high risk of infection and lower-limb amputation. Ulcers are deemed neuroischaemic if peripheral neuropathy and peripheral artery disease are both present. No satisfactory treatment for neuroischaemic ulcers currently exists, and no evidence supports one particular dressing. We aimed to assess the effect of a sucrose octasulfate dressing versus a control dressing on wound closure in patients with neuroischaemic diabetic foot ulcers.

Methods

We did a randomised, double-blind clinical trial (Explorer) in 43 hospitals with specialised diabetic foot clinics in France, Spain, Italy, Germany, and the UK. Eligible participants were inpatients or outpatients aged 18 years or older with diabetes and a non-infected neuroischaemic diabetic foot ulcer greater than 1 cm^2 and of grade IC or IIC (as defined by the University of Texas Diabetic Wound Classification system). We excluded patients with a severe illness that might lead to them discontinuing the trial and those who had surgical revascularisation in the month before study entry. We randomly assigned participants (1:1) via a computer-generated randomisation procedure (concealed block size two); stratified by study centre and wound area (1–5 cm^2 and 5–30 cm^2), to treatment with either a sucrose octasulfate wound dressing or a control dressing (the same dressing without sucrose octasulfate) for 20 weeks. Both groups otherwise received the same standard of care for a 2-week screening period before randomisation and throughout the 20-week trial. Dressings were applied by nursing staff (or by instructed relatives for some outpatients). Frequencies of dressing changes were decided by the investigator on the basis of the clinical condition of the wound. Patients were assessed 2 weeks after randomisation, then monthly until week 20 or occurrence of wound closure. The primary outcome, assessed by intention-to-treat, was proportion of patients with wound closure at week 20. This trial is registered with ClinicalTrials.gov, number NCT01717183.

Findings

Between March 21, 2013, and March 31, 2016, we randomly assigned 240 individuals to treatment: 126 to the sucrose octasulfate dressing and 114 to the control dressing. After 20 weeks, wound closure occurred in 60 patients (48%) in the sucrose octasulfate dressing group and 34 patients (30%) in the control dressing group (18 percentage points difference, 95% CI 5–30; adjusted odds ratio 2·60, 95% CI 1·43–4·73; p=0·002). In both groups, the most frequent adverse events were infections of the target wound: 33 wound infections in 25 (20%) patients of 126 in the sucrose octasulfate dressing group and 36 in 32 (28%) patients of 114 in the control dressing group. Minor amputations not affecting the wound site were also reported in one (1%) patient in the sucrose octasulfate dressing group and two (2%) patients in the control dressing group. Three (2%) patients assigned to the sucrose octasulfate dressing and four (4%) assigned to the control dressing died, but none of the deaths were related to treatment, procedure, wound progression, or subsequent to amputation.

Interpretation

A sucrose octasulfate dressing significantly improved wound closure of neuroischaemic diabetic foot ulcers without affecting safety after 20 weeks of treatment along with standard care. These findings support the use of sucrose octasulfate dressing as a local treatment for neuroischaemic diabetic foot ulcers.

Funding

Laboratoires Urgo Medical.