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Phototherapy for treating foot ulcers in people with diabetes

Review

Intervention

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Abstract

Background

Foot ulcers are a disabling complication of diabetes that affect 15% to 25% of people with diabetes at some time in their lives. Phototherapy is a relatively new, non-invasive, and pain-free treatment method, which promotes the ulcer repair process through multiple mechanisms such as increased cell growth and vascular activity. Phototherapy may be used as an alternative approach for the treatment of foot ulcers in people with diabetes, but the evidence for its effect compared with placebo or other treatments has not yet been established.

Objectives

To assess the effects of phototherapy for the treatment of foot ulcers in people with diabetes.

Search methods

We searched the Cochrane Wounds Specialised Register (11 October 2016), the Cochrane Central Register of Controlled Trials (CENTRAL) (the Cochrane Library, 2016, Issue 10), Ovid MEDLINE (11 October 2016), Ovid MEDLINE (In-Process & Other Non-Indexed Citations) (11 October 2016), Ovid Embase (11 October 2016), EBSCO CINAHL Plus (11 October 2016), and China National Knowledge Infrastructure (24 June 2017). We also searched clinical trials registries for ongoing and unpublished studies on 24 June 2017, and screened reference lists to identify additional studies. We used no restrictions with respect to language, date of publication, or study setting.

Selection criteria

Randomised controlled trials or cluster randomised controlled trials that 1) compared phototherapy with sham phototherapy, no phototherapy, or other physical therapy modalities, 2) compared different forms of phototherapy, or 3) compared phototherapy of different output power, wavelength, power density, or dose range, in adults with diabetes and an open foot ulcer of any severity, in any setting.

Data collection and analysis

Two review authors independently performed study selection, data extraction, and 'Risk of bias' assessment. We combined the study outcomes when appropriate.

Main results

Eight trials with 316 participants met the inclusion criteria. Most of the included studies were single-centre studies that were carried out in clinics or hospitals with a sample size ranging from 14 to 84. We generally considered the included studies to be at unclear or high risk of bias, as they had one domain at high risk of bias, or three or more domains at unclear risk of bias.

We did not identify any studies that reported valid data for time to complete wound healing. Meta-analysis of four studies including 116 participants indicated that participants receiving phototherapy may experience a greater proportion of wounds completely healed during follow-up compared with those receiving no phototherapy/placebo (64.5% for the phototherapy group versus 37.0% for the no phototherapy/placebo group; risk ratio 1.57, 95% confidence interval 1.08 to 2.28; low-quality evidence, downgraded for study limitations and imprecision). Two studies mentioned adverse events in the results; one study with 16 participants suggested that there were no device-related adverse events, and the other study with 14 participants suggested that there was no clear difference between phototherapy and placebo group. Four studies reported change in ulcer size, but primarily due to high heterogeneity, they were not combined. Results from individual trials (including 16 participants to 84 participants) generally suggested that after two to four weeks of treatment phototherapy may result in a greater reduction in ulcer size but the quality of the evidence was low due to unclear risk of bias in the original trial and small sample size. We based the analyses for quality of life and amputations on only one study each (28 participants and 23

participants respectively); both outcomes showed no clear difference between the phototherapy group and the no phototherapy/placebo group.

Authors' conclusions

This systematic review of randomised trials suggested that phototherapy, when compared to no phototherapy/placebo, may increase the proportion of wounds completely healed during follow-up and may reduce wound size in people with diabetes, but there was no evidence that phototherapy improves quality of life. Due to the small sample size and methodological flaws in the original trials, the quality of the evidence was low, which reduces our confidence in these results. Large, well-designed randomised controlled trials are needed to confirm whether phototherapy could be an effective option for the treatment of foot ulcers in people with diabetes.

Plain language summary

English

Phototherapy for treating foot ulcers in people with diabetes

Review question

Phototherapy is a pain-free method of treatment that uses light to treat various medical conditions. We reviewed the evidence about phototherapy for foot ulcers in people with diabetes. We wanted to find out whether phototherapy speeds up wound healing and improves patients' quality of life, and whether there are any side effects.

Background

Foot ulcers are a disabling complication of diabetes that affect 15% to 25% of people with diabetes at some time in their lives. Diabetic foot ulcers are painful and prone to infection. Not all diabetic foot ulcers can be healed, which can ultimately lead to surgical removal of a limb. Phototherapy involves exposing the affected area to ultraviolet light, sometimes using lasers. This is thought to help ulcers heal through multiple mechanisms such as increased cell growth and blood vessel activity. It has been used as an alternative approach for healing foot ulcers in people with diabetes.

Study characteristics

We searched for randomised controlled trials comparing different phototherapies, or comparing phototherapy with other treatments or a placebo (sham treatment), for foot ulcers in adults with diabetes in October 2016. We included eight trials (316 participants). Most studies were undertaken in clinics or hospitals and had small numbers of participants (14 to 84). The average age in the included studies was from 53 to 68 years, and the ratio of females to males was 0.46 to 1.88. The included studies compared phototherapy with placebo or no phototherapy, on top of usual care (usual care could include treatments such as dressings, antibiotics, or wound cleaning). Treatment times ranged from 15 days to 20 weeks.

Key results

The results suggested that phototherapy, when compared to no phototherapy or a placebo, may increase the proportion of wounds completely healed during follow-up and reduce wound size. However, as the included studies involved small numbers of

participants and had drawbacks in study methods, our confidence in these results is limited. We did not find sufficient evidence that the potential harms or incidence of amputations differed between the phototherapy group and the no phototherapy/placebo group.

Quality of the evidence

We judged the quality of the evidence to be low due to a lack of data and risk of the study results being biased. Further high-quality studies are needed to confirm the benefits and harms of phototherapy.

This plain language summary is up to date as of 26 October 2016.

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