

Antibiotics and antiseptics for venous leg ulcers - Cochrane Review 2010

Summary

The objective of the systematic review was to determine the effects of systemic antibiotics, topical antibiotics and antiseptics on the healing of venous leg ulcers. The review concluded that:

- There was some evidence to suggest that **cadexomer iodine generates higher healing rates than standard care in venous leg ulcers**.
- Further good quality research was required before definitive conclusions can be made about the effectiveness of systemic antibiotics and topical preparations such as povidone iodine, peroxide based preparations, ethacridine lactate, mupirocin and chlorhexidine in healing venous leg ulcers.

The review identified a **total of ten RCTs recruiting 645 patients in support of cadexomer iodine** in the healing of venous leg ulcers, the findings of which were as follows:

Cadexomer iodine vs standard care

A total of 4 RCTs were identified. Lindsay¹ conducted a 28 patient study in a community setting comparing outcomes at 4 weeks (N=25) between cadexomer iodine and standard care which included topical antimicrobial interventions in some cases. Laudanska² recruited 67 patients in a hospital setting comparing cadexomer iodine with standard dressings (zinc paste dressing) over a 6 week period. Ormiston³ recruited 61 patients in the outpatient setting, patients were treated for 24 weeks or until healing, with an optional cross-over at 12 weeks. Holloway⁴ recruited 75 patients in an outpatient setting and followed them up for 24 weeks.

Frequency of complete healing

Lindsay¹ reported a larger number of patients in the cadexomer iodine group ($\frac{1}{2}$; 33%) were healed after 4 weeks than in the standard care group ($\frac{1}{3}$, 8%), however this difference was not statistically significant. **Laudanska² reported statistically significant evidence (p<0.05) that more patients' ulcers healed or became very superficial in the cadexomer iodine group ($\frac{15}{30}$; 57%) than in the standard care group ($\frac{7}{30}$; 20%) (RR 2.29, 95% CI 1.10, 4.74).** It was however stated that this trial is likely to lack external validity in light of the study regimen (i.e hospital admission, bed rest and daily dressing changes). In the Ormiston³, a total of $\frac{12}{30}$ (40%) patients in the cadexomer iodine group and $\frac{7}{30}$ (23%) in the standard care group were healed by week 12.

This difference was not statistically significant (RR 1.71, 95% CI 0.78 to 3.75).

Change in ulcer area

Both Lindsay¹ and Laudanska² reported a **statistically significant greater mean percentage reduction in wound area in the cadexomer iodine group in comparison to standard care**. At 4 weeks 33.6% vs 4.2%, p<0.005 (Lindsay¹); at 6 weeks 71% vs 54%, p<0.001 (Laudanska²).

Rate of reduction in ulcer area

When data from the Holloway⁴ and Ormiston³ studies were pooled, there was **significant evidence (p<0.05) of a faster healing rate in the cadexomer iodine group than in the standard care group** (mean difference 0.47 cm² per week, 95% CI 0.26 to 0.69).

Cadexomer iodine plus compression vs standard care plus compression

Three trials were identified. Harcup⁵ recruited 72 patients in the outpatient setting, following up for 4 weeks. Skog⁶ recruited 93 patients in the outpatient setting following up for 6 weeks and Steele⁷ recruited 60 patients, where dressings were changed 3 times per week for 6 weeks in the community setting.

Frequency of complete healing

After data from 2 trials (Steele⁷ and Harcup⁵) were pooled, there was **statistically significant evidence in favour of cadexomer iodine in terms of the frequency of complete healing at weeks 4 to 6** (RR6.72, 95% CI 1.56 to 28.95).

Change in ulcer area

Two trials reported **statistically significant mean reductions in ulcer area in the cadexomer iodine group relative to controls**: 66% compared with 44% reduction at 8 weeks, p<0.01 (Harcup⁵); and a 34% reduction vs an increase of 5% at 6 weeks, p<0.02 (Skog⁶).

Bacterial eradication

Skog⁶ observed a statistically significant decrease in *Staph aureus* in the cadexomer iodine group when compared with controls (RR 31.31, 95% CI 1.95 to 503.29).

Cadexomer iodine vs dextranomer

Two trials were identified, both in outpatient settings. Kero⁸ recruited 27 patients and Moss⁹ recruited 42 patients.

Frequency of complete healing

After 8 weeks a larger number of patients achieved complete healing in the cadexomer iodine group (71%; 64.5%) than in the dextranomer group (50%; 50%), although this difference was not statistically significant (RR 1.27, 95% CI 0.59 to 2.73 (based on 21 patients, Kero⁸).

Change in ulcer area

Kero⁸ reported a larger mean reduction in ulcer area in the cadexomer iodine group, although the difference was not statistically significant: 81% compared with 35% reduction at 8 weeks. Moss⁹ reported a similar mean reduction in ulcer area after 6 weeks for the 2 groups: 2% (dextranomer) compared with 3% (cadexomer iodine).

Cadexomer iodine vs hydrocolloid and paraffin gauze

One trial was identified. Hansson¹⁰ conducted a multi-centre trial recruiting 153 patients in an outpatient setting. Patients with exuding, non-infected venous leg ulcers were included and were followed up for 12 weeks or until exudation ceased.

Frequency of complete healing

There was no evidence of a difference in the frequency of wound healing between cadexomer iodine and the hydrocolloid and paraffin gauze groups. After 12 weeks the numbers of healed wounds were as follows: 14% (14%) in the cadexomer iodine group, 10% (10%) in the hydrocolloid group and 14% (14%) in the paraffin gauze group.

Change in ulcer area

There was **significant evidence of a greater mean percentage reduction in wound area for the cadexomer iodine group** after 12 weeks in comparison to both the hydrocolloid group (mean difference 20.9%, 95% CI 2.22 to 39.58) and the paraffin gauze group (mean difference 37.7%, 95% CI 8.77 to 66.63).

Rate of reduction in wound area

No evidence of a difference in the mean percentage reduction in wound area per week between the cadexomer iodine group (8% per week) and the hydrocolloid group (9% per week), but significant evidence of a larger rate of

reduction for the cadexomer iodine group in comparison to paraffin gauze group (3% per week, mean difference 6.00%, 95% CI 1.56 to 10.44).

Cost

The **costs of treatment taking into account staff time, materials and transport** and presented in terms of US\$ per % ulcer area reduction **was lower for the cadexomer iodine group** (\$8.8) relative to the hydrocolloid group (\$32.5) and the paraffin gauze group (\$12.9). It was presumed that the 1998 price year was used.

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66001291	IODOSORB 10g	3 Dressings
66001292	IODOSORB 10g	5 Dressings
66001293	IODOSORB 17g	2 Dressings
66001301	ODOFLEX 5g	5 Dressings
66001302	ODOFLEX 10g	3 Dressings
66001303	ODOFLEX 17g	2 Dressings

IODOSORB Ointment

Code	Size	Pack Quantity
66001298	10g	4 Tubes
66001297	20g	2 Tubes
66001299	40g	1 Tube

IODOSORB Powder

Code	Size	Pack Quantity
66001286	3g	7 Sachets
66001288	50g	1 Tube

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Smith & Nephew
Medical Ltd
101 Hessle Road
Hull HU3 2BN
UK

www.smith-nephew.com
www.iodosorb.com

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T +44 (0) 1482 225181
F +44 (0) 1482 328326

