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[Intervention Review]

Sulodexide for treating venous leg ulcers

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ABSTRACT

Background

Venous leg ulcers are common, chronic wounds caused by venous diseases, with a high recurrence rate and heavy disease burden. Compression therapy (bandages or stockings) is the first choice treatment for venous leg ulcers. However, when ulcers remain unhealed, medication can also be used with or without compression therapy. Sulodexide, a highly purified glycosaminoglycan (a naturally occurring molecule) has antithrombotic and profibrinolytic properties (it reduces the formation of blood clots) as well as anti-inflammatory effects. Sulodexide has been studied as a potential treatment for venous leg ulcers.

Objectives

To assess the efficacy and safety of sulodexide for treating venous leg ulcers.

Search methods

In July 2015 we searched: The Cochrane Wounds Specialised Register; The Cochrane Central Register of Controlled Trials (CENTRAL) (*The Cochrane Library*); Ovid MEDLINE; Ovid MEDLINE (In-Process & Other Non-Indexed Citations); Ovid EMBASE; EBSCO CINAHL; Chinese Biomedical Literature Database (CBM); China National Knowledge Infrastructure Database (CNKI); Wan Fang and VIP. We also searched clinical trials registries to identify ongoing studies, as well as references listed in relevant publications. There were no restrictions based on date of publication, language or study setting.

Selection criteria

Randomised controlled trials (RCTs) involving people with a diagnosis of venous leg ulcers which compared sulodexide with placebo or any other drug therapy (such as pentoxifylline, flavonoids, aspirin), with or without compression therapy.

Data collection and analysis

We used standard Cochrane methodological procedures. The authors independently selected studies, extracted data and assessed risk of bias. We pooled data to present the risk ratio (RR) with 95% confidence interval (CI), or presented a narrative summary. We assessed overall evidence quality according to the GRADE approach.

Main results

We included four RCTs with a total of 463 participants (aged 42 years to 93 years); one report was only available as a published abstract.

Meta-analysis of three RCTs suggests an increase in the proportion of ulcers completely healed with sulodexide as an adjuvant to local treatment (including wound care and compression therapy) compared with local treatment alone (rate of complete healing with sulodexide 49.4% compared with 29.8% with local treatment alone; RR 1.66; 95% CI 1.30 to 2.12). This evidence for sulodexide increasing the rate

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of complete healing is low quality due to risk of bias. It is unclear whether sulodexide is associated with any increase in adverse events (4.4% with sulodexide versus 3.1% with no sulodexide; RR 1.44; 95% CI 0.48 to 4.34). The evidence for adverse events is very low quality, downgraded twice for risk of bias and once for imprecision.

Authors' conclusions

Sulodexide may increase the healing of venous ulcers, when used alongside local wound care, however the evidence is only low quality and the conclusion is likely to be affected by new research. It is not clear whether sulodexide is associated with adverse effects. The standard dosage, route and frequency of sulodexide reported in the trials was unclear. Further rigorous, adequately powered RCTs examining the effects of sulodexide on healing, ulcer recurrence, quality of life and costs are necessary.

PLAIN LANGUAGE SUMMARY

Sulodexide for venous leg ulcers

Review question

We reviewed the evidence about the effect of sulodexide on people with venous leg ulcers.

Background

Venous leg ulcers are a common, chronic and recurring wound on people's legs. Venous leg ulcers are caused by venous disease, particularly in the elderly. Compression therapy (usually using bandages or stockings) is the first choice of treatment for venous leg ulcers. However, compression therapy is not suitable for some people, and some ulcers remain unhealed with compression. Sulodexide (a medicine which reduces blood clotting) has been studied as a treatment for venous leg ulcers. We wanted to find out if there is good evidence for sulodexide improving venous ulcer healing.

Study characteristics

The review includes four studies involving 463 people with venous leg ulcers aged between 42 and 93 years old. The studies compared sulodexide used in combination with local treatment (including wound care and compression therapy) with local treatment alone. The duration of the four studies ranged from one month to three months.

Key results

Three studies (438 participants) indicated that sulodexide might help to improve ulcer healing, as the proportion of ulcers that were completely healed was increased from 29.8% with local treatment to 49.4% when the participants also received sulodexide. It is unclear whether sulodexide results in more adverse effects (4.4% with sulodexide versus 3.1% without sulodexide).

Quality of the evidence

The overall quality of evidence for each outcome varied between low and very low, due to risk of bias, and imprecision (that is, for some outcomes, results from only one, small study were available).

This plain language summary is up to date as of 1 July 2015.