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[Intervention Review]

Phlebotonics for haemorrhoids

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ABSTRACT

Background

Haemorrhoids are variceal dilatations of the anal and perianal venous plexus and often develop secondary to the persistently elevated venous pressure within the haemorrhoidal plexus (Kumar 2005). Phlebotonics are a heterogenous class of drugs consisting of plant extracts (i.e. flavonoids) and synthetic compounds (i.e. calcium dobesilate). Although their precise mechanism of action has not been fully established, they are known to improve venous tone, stabilize capillary permeability and increase lymphatic drainage. They have been used to treat a variety of conditions including chronic venous insufficiency, lymphoedema and haemorrhoids.

Numerous trials assessing the effect of phlebotonics in treating the symptoms and signs of haemorrhoidal disease suggest that there is a potential benefit.

Objectives

The aim of this review was to investigate the efficacy of phlebotonics in alleviating the signs, symptoms and severity of haemorrhoidal disease and verify their effect post-haemorrhoidectomy.

Search methods

We searched the Cochrane Central Register of Controlled Trials (CENTRAL) in the Cochrane Library 2011 issue 9, MEDLINE (1950 to September 2011) and EMBASE (1974 to September 2011).

Selection criteria

Only randomised controlled trials evaluating the use of phlebotonics in treating haemorrhoidal disease were used. No cross-over or cluster-randomized trials were included for analysis and any trial which had a quasi-random method of allocation was excluded.

Data collection and analysis

Two authors independently extracted the data and analysed the eligibility of the data for inclusion. Disagreements were resolved by meaningful discussion.

Main results

We considered twenty-four studies for inclusion in the final analysis. Twenty of these studies (enrolling a total of 2344 participants) evaluated the use of phlebotonics versus a control intervention. One of these twenty studies evaluated the use of phlebotonics with a medical intervention and another study with rubber band ligation.

The remaining four studies included two which compared different forms of phlebotonics with each other, one study which evaluated phlebotonics with a medical intervention and one study which compared the use of phlebotonics with infrared photocoagulation. Eight studies were excluded for various reasons including poor methodological quality.

Phlebotonics demonstrated a statistically significant beneficial effect for the outcomes of pruritus (OR 0.23; 95% CI 0.07 to 0.79) (P=0.02), bleeding (OR 0.12; 95% CI 0.04 to 0.37) (P=0.0002), bleeding post-haemorrhoidectomy (OR 0.18; 95% 0.06 to 0.58)(P=0.004), discharge and leakage (OR 0.12; 95% CI 0.04 to 0.42) (P=0.0008) and overall symptom improvement (OR 15.99 95% CI 5.97 to 42.84) (P< 0.00001), in comparison with a control intervention. Although beneficial they did not show a statistically significant effect compared with a control intervention for pain (OR 0.11; 95% CI 0.01 to 1.11) (P=0.06), pain scores post-haemorrhoidectomy (SMD -1.04; 95% CI -3.21 to 1.12) (P= 0.35) or post-operative analgesic consumption (OR 0.54; 95% CI 0.30 to 0.99)(P=0.05).

Authors' conclusions

The evidence suggests that there is a potential benefit in using phlebotonics in treating haemorrhoidal disease as well as a benefit in alleviating post-haemorrhoidectomy symptoms. Outcomes such as bleeding and overall symptom improvement show a statistically significant beneficial effect and there were few concerns regarding their overall safety from the evidence presented in the clinical trials.

However methodological limitations were encountered. In order to enhance our conclusion further, more robust clinical trials which take into account these limitations will need to be performed in the future.

PLAIN LANGUAGE SUMMARY

Phlebotonics for haemorrhoids

Haemorrhoids are among the most common benign anorectal pathologies which usually manifest with the common symptoms and signs of bleeding, pain, pruritus, swelling and discharge. The prevalence can vary from 4.4% in the general population to 36.4% in general practice. However their true prevalence will inevitably be underestimated due to the under-reporting of these symptoms. Medical and conservative management with high-fibre diets, stool softeners and laxatives are the preferred treatments for grade I-II haemorrhoids whereas surgical procedures such as haemorrhoidectomy are reserved for the more severe forms of haemorrhoids. Phlebotonics are a heterogeneous class of drugs used to treat haemorrhoidal disease in the less severe stages of first and second-degree haemorrhoids, and during the thrombosis episodes. Although their true mechanism of action has not been well established, they are associated with strengthening of blood vessel walls, increasing venous tone, lymphatic drainage and normalizing capillary permeability. We considered twenty four studies for inclusion in this review. This review identified twenty randomised controlled trials enrolling a total of (2334) participants which compared an intervention using phlebotonics with a control intervention. Of these twenty studies, one study compared phlebotonics with a medical intervention and another with rubber band ligation. Of the remaining four trials, we identified two trials which compared phlebotonics with each other, one trial which compared phlebotonics with herbal therapy and one trial which compared phlebotonics with infrared photocoagulation. The trials obtained did not show any significant adverse events or side-effects from the use of phlebotonics. The studies demonstrated a beneficial effect of phlebotonics in treating the symptoms and signs of haemorrhoidal disease as well as symptom relief post-haemorrhoidectomy.