

engle34 translation

## ***The use of PHLEBODIA® in the management of bleeding non-prolapsed haemorrhoids***

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### **ABSTRACT**

The aim of this study is to describe the role of diosmin in the management of bleeding non-prolapsed haemorrhoids. From November 2003 to January 2004, a group of 60 patients with non-prolapsed bleeding haemorrhoids (gradus II) was treated with Phlebodia (diosmin). Total colonoscopy was performed in 18 patients before starting the treatment, at the discretion of the investigators according to the symptoms and the age of the patient as well as to genetic factors of the patient. Diosmin (2x1 daily for 5 days according to the recepture) and herbal laxant *Plantago ovata* (2 sachets daily over 3 months period) were administrated to all patients. Haemorrhoidal bleeding stopped after 3,2 days on the average. Complications or undesirable effects were not observed.

The use of Phlebodia (with addition of the herbal laxant *Plantago ovata* which accelerates the cease of haemorrhoidal bleeding) can be an efficient, safe and non-invasive method for management of non-prolapsed bleeding haemorrhoids.

Key words: diosmin, non-prolapsed bleeding haemorrhoids, *plantago ovata*

### **1. INTRODUCTION**

Haemorrhoids are part of normal human anatomy. External haemorrhoids originate from lower haemorrhoidal plexus and they are covered with modified squamous epithel distally from the dentate line. They can become enlarged or thrombosed causing pain or they can ulcerate with subsequent bleeding. Thrombosis can be healed or a skin tag can remain causing itching, burning or staining.

Internal haemorrhoids are classified in 4 stages:

1. First grade haemorrhoids originate from the sub-mucous vascular tissue that is located above the dentate line. They can increase in number and size and bleed after defecation. They project into the lumen and can be seen with the anoscope but they do not prolapse.
2. Second grade haemorrhoids come out but they spontaneously return after the straining stops. They can bulge into the lumen of the anoscope.
3. Third grade haemorrhoids prolapse during defecation and can be seen outside the anus during physical examination. Periodical or repeated manual replacement is necessary.
4. Fourth grade haemorrhoids are always prolapsed. They can thrombose.

Internal haemorrhoids originate from upper haemorrhoidal plexus and they are covered with mucosa proximal to the dentate line. Symptomatic internal haemorrhoids can cause

burning, enlargement, itching, pain, prolapse, discharge, bleeding and/or staining underwear.

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An ideal medication in the management of bleeding non-prolapsed haemorrhoids would be the medication which could lead to quick withdrawal of symptoms (pains and/or bleeding) with minimal risk of an early relapse and complications. Chopped membranes of Asian plantain seeds, *Plantago ovata*, can be efficient in these cases but the relapse of bleeding is possible. Techniques as application of elastic ligatures and sub-mucous injections can stop the bleeding more quickly. The use of *Plantago ovata* is very significant in attaining long-term cure after the placement of elastic ligatures. The preparation with the active substance diosmin (PHLEBODIA® 600 mg, Innotech International, France) increases venous tonus (without affecting the arterial vessels), has an anti-inflammatory and anti-oedematous effect and is a very efficient, non-invasive medicine for treatment of bleeding non-prolapsed haemorrhoids.

Diosmin inhibits inflammatory response path and maintains integrity of the capillary endothelium (by inhibiting adhesion and migration of leucocytes as well as protein passage through the endothelium). The venous tonus was improved by prolonged effect of norepinephrine in the vein wall. It is assumed that diosmin inhibits COMT, decreases noradrenaline metabolism in tissues increasing local concentration by doing so and leads to increased venous tonus. Oedema was reduced by increasing the oncotic pressure which favours the lymphatic drainage.

#### PATIENTS AND METHODS

60 patients with bleeding non-prolapsed haemorrhoids were included in the study and they were observed for 3 months. In order to exclude malignant or other diseases which can have similar symptoms, total colonoscopy was performed in 18 patients, at the discretion of the investigators according to the symptoms and the age of the patient as well as to genetic factors of the patient. Diosmin (PHLEBODIA® 600 mg, Innotech International, France, for 5 days, three times daily with appropriate dietetic regime (avoiding sharp and spicy foods, hard alcoholic liquor etc.) and 2 sachets of 3,26 g of *plantago ovata*, were administrated to all patients for the next 3 months.

The first check-up examination was performed after one week to establish the exact time the bleeding had stopped, and then after 3 months to establish possible relapse of the disease. Haemorrhoid ligation was performed in all patients who did not show response to treatment and herbal laxant was proscribed. If difficulties did not stop after this, haemorrhoidectomy was performed.

#### RESULTS

The average patients' age was 44,7 years. 30 men and 30 woman were included in the study. Bleeding from internal non-prolapsed haemorrhoids stopped after 3,2 days on the

average. Bleeding in one patient stopped one day after administration of the therapy, in 5 patients after 2 days, in 40 patients after 3 days, in 10 patients after 4 days and in 4 of them after 5 days (Chart 1). Repeated bleeding occurred in 2 patients, it was managed by application of elastic ligatures in one patient and by haemorrhoidectomy in other patient. There were no undesirable effects.

## DISCUSSION

It was shown that *Plantago ovata* can lead to the cease of bleeding by itself, but the relapse is possible and relatively frequent in the first 6 weeks after the treatment. The time period when the cease of bleeding occurs (3,2 days on the average) significantly reduces with the use of Phlebodia, with addition of fibre preparations. By comparing results of Phlebodia with the results obtained by application of elastic ligatures in one session, it is obvious that bleeding stops in 5,6 days on the average after the application of elastic ligatures and that it is most likely the result of minimal injuries of rectal mucosa that occur when placing elastic ligatures.

Incidence of false urges and pains occurring always after the placement of elastic ligatures, in single episodes or jointly, was not observed with the use of Phlebodia.

Although according to information from literature there is no statistically significant difference in attaining the cease of bleeding in patients receiving Phlebodia compared to ones who had the elastic ligatures placed, it is very important to emphasise that this medicine can be proscribed by both family doctors and physicians who are not familiar with the application of elastic ligatures. Of course, it should be mentioned that the existence of carcinoma of the rectum or other diseases causing bleeding should be excluded first.

### ***PHLEBODIA (diosmin): A role in the management of bleeding non-prolapsed haemorrhoids***

#### ABSTRACT

The aim of this study is to describe a role of diosmin in the management of bleeding non-prolapsed haemorrhoids. From November 2003 to January 2004, 60 patients were treated with Phlebodia (diosmin). Total colonoscopy was performed at the discretion of the authors according to the age, symptoms and genetic factors of the patient. Patients were treated with Phlebodia (diosmin, 3x1, 5 days) and in addition a bulk agent (3,26 g *plantago ovata* sachet, twice daily, for the period of next three months). Haemorrhoidal bleeding stopped after 3,2 days.

Used with fibre supplements, diosmin rapidly and safely stops bleeding from non-prolapsed haemorrhoids.

Key words: diosmin, non-prolapsed bleeding haemorrhoids, *plantago ovata*