Indigenous Drug Therapy for Haemorrhoids

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Haemorrhoids is one of the common conditions encountered in general surgical practice. It is the price which man has to pay for adopting an erect posture, causing morbidity due to discomfort, pain and bleeding, often leading to generalised weakness and anaemia.

Treatment of haemorrhoids varies according to the degree. Local injection of sclerosing agents is advisable for first and second degree haemorrhoids. For other types, haemorrhoidectomy is the treatment of choice. However, surgical treatment requires a long period of hospitalisation, besides the availability of a trained surgeon. Both may not be available to many, particularly in the rural areas.

The management of haemorrhoids with indigenous herbal medicines has been in practice since long. The patient undergoing this treatment remains ambulatory, without disturbing his routine schedule of work.

MATERIAL AND METHODS

Very few controlled trials have been done using indigenous herbal therapy. The present paper envisages a prospective double blind study conducted in a single unit at the All-India Institute of Medical Sciences, New Delhi, during the period July 1977-July 1978. The drug used in the trial was Pilex, both tablets and ointment.

The present trial was conducted on those patients where there was no indication for operation. They were cases of first and second degree uncomplicated haemorrhoids.

Age and Sex

A total of one hundred patients were studied. Fifty patients were given a placebo and the remaining fifty patients were treated with the standard regimen of Pilex therapy. The fifty patients treated with Pilex were distributed as under:

<table>
<thead>
<tr>
<th>Age group in years</th>
<th>Number of patients</th>
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</thead>
<tbody>
<tr>
<td>20 - 40</td>
<td>44</td>
</tr>
<tr>
<td>41 – 60</td>
<td>6</td>
</tr>
</tbody>
</table>

There were thirty-five males and fifteen females.

Symptoms

Bleeding was the most common symptom in all the patients. Ninety-two per cent of the patients complained of pain during or after defaecation. There was mucus discharge in 72 per cent of the cases.
<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Percentage of cases</th>
</tr>
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<tbody>
<tr>
<td>Bleeding</td>
<td>100% (all cases)</td>
</tr>
<tr>
<td>Pain during or after defaecation</td>
<td>92%</td>
</tr>
<tr>
<td>Mucus discharge</td>
<td>72%</td>
</tr>
</tbody>
</table>

**Physical Findings**
A detailed history was taken in all the cases to exclude any other cause of bleeding per rectum, than haemorrhoids. Digital and routine proctoscopic examinations were done in all cases to exclude associated rectal conditions. Haemoglobin and stool examinations were done routinely.

First degree haemorrhoids occurred in twenty-eight patients and second degree in twenty-two patients in the Pilex group. Of the patients treated with placebo, sixty per cent had first degree haemorrhoids.

**COMPOSITION**
Each Pilex tablet contains:
- Balsamodendron mukul 0.13 g
- Melia azadirachta seeds 7 mg
- Shilajit (Purified) 16 mg
- Ext. Phyllanthus emblica 16 mg
  - Terminalia chebula 16 mg
  - Terminalia belerica 16 mg
  - Berberis aristata 32 mg
  - Arisaema wallichianum 3 mg
  - Cassia fistula 16 mg
  - Bauhinia variegata 16 mg

Processed in Commelina salicifolia, Mimosa pudica, Acorus calamus, Blumea lacera, Caesalpinia bonducella and Amorphophallus campanulatus.

Pilex Ointment contains:
- Ext. Mimosa pudica 5%
- Vitex negundo 3%
- Calendula officinalis 2%
- Eclipta alba 3%
- Aesculus hippocastanum 2%
- Camphor 1.225%
- Base q.s. ad. 100%

Processed in Melia azadirachta, Ailanthus excelsa, Blumea balsamifera, Eclipta alba, Allium ascalonicum, Acorus calamus, Solanum nigrum, Mimosa pudica.

The therapeutic effects of various ingredients in Pilex are stated to be anti-inflammatory, demulcent, laxative and styptic.

**Dosage Schedule**
Initially Pilex tablets were given in a dose of two tablets thrice daily for one week, followed by two tablets twice daily for four weeks. A maintenance dose of one tablet twice daily was given till symptomatic relief was obtained. This period varied from a few weeks to a few months. Pilex ointment was used in all patients as a supplement to the tablets.
OBSERVATIONS

**Pilex Group**
Remarkable improvement in the form of complete cessation of bleeding, pain and discharge was seen in 50 per cent of cases. Proctoscopy in these patients revealed significant shrinkage of the pile masses and improvement in the haemoglobin level.

Good response in the form of marked regression of bleeding, pain and discharge occurred in 26 per cent of cases. Proctoscopy revealed shrinkage of pile mass to a lesser extent.

Poor response, either subjectively or objectively, was seen in 24 per cent of cases. All cases have been followed up for six to eight months.

**Placebo Group**
In first degree haemorrhoids, significant improvement in the form of complete cessation of bleeding, pain and discharge was seen only in 20 per cent of cases. Ten per cent of the cases had some improvement in their symptoms with some shrinkage of pile masses and reduction in discharge. The remaining 70 per cent of patients had a poor subjective or objective response in the follow-up period of 6 months. Several of them subsequently changed over to some other form of therapy like injection and surgery as they were unwilling for any other trial.

<table>
<thead>
<tr>
<th>Response</th>
<th>Pilex Group (%)</th>
<th>Placebo Group (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very good</td>
<td>50</td>
<td>20</td>
</tr>
<tr>
<td>Good</td>
<td>26</td>
<td>10</td>
</tr>
<tr>
<td>Poor</td>
<td>24</td>
<td>70</td>
</tr>
</tbody>
</table>

SUMMARY
- Fifty patients with haemorrhoids were managed conservatively with Pilex ointment and tablets and 50 were given Placebo.
- Of the patients treated with Pilex, 35 were males and 15 were females. In the placebo group, there were 32 males and 18 females.
- Bleeding, pain and discharge were the common symptoms.
- Majority of the patients had first degree haemorrhoids.
- All patients were followed-up for six to eight months.
- Results of treatment with Pilex were highly satisfactory while they were unsatisfactory in the placebo group. In the trial group on Pilex, the results were very good in 50% cases and good in 26% cases. In 24% cases, however, the response was poor.

ACKNOWLEDGEMENTS
We are grateful to The Himalaya Drug Company, for providing Pilex tablets and ointment, and the help given for this study.
REFERENCES