INTRODUCTION
Piles are one of the commonest ailments that affect mankind. Clinical experience suggests that a large number of people of both sexes suffer from haemorrhoids and that perhaps even more have piles in a symptomless form. The term ‘haemorrhoids’ is of Greek origin and cannot be applied to all the cases, as quite a few of them do not suffer from bleeding.

The term ‘pile’ is derived from the Latin word ‘Pila’ a ball. It can be aptly used for all forms of haemorrhoids or piles, for literally every such condition does produce a swelling of some kind.

Classification: Haemorrhoids are classified into 3 degrees.

1. First-degree: Haemorrhoids that prolapse sufficiently to be nipped by the anal sphincter for a moment on defaecation are called first degree piles.

2. Second-degree: Haemorrhoids that prolapse while the patient is straining during defaecation but need to be replaced manually and then stay reduced are second-degree haemorrhoids.

3. Third-degree: Haemorrhoids that are permanently prolapsed are called third-degree haemorrhoids.

PATHOLOGICAL ANATOMY
Internal piles are essentially varicosities of the venous plexuses in the wall of the anal canal and lower most half inch or so of the rectum. These form a swelling covered with mucosa and bulge into the lumen of the anal canal; this is specially so when portal venous pressure is raised and the sphincter is relaxed during defaecation. Internal haemorrhoids in association with the terminal divisions of the superior rectal artery are arranged in three groups at 3, 7 and 11 o’clock positions, when a patient is seen in the lithotomy position. The veins concerned chiefly in forming the haemorrhoids are mainly those of the submucous or internal haemorrhoidal plexus which are radicals of the superior rectal vein. The superior rectal vein has no valves so the vein has to support the pressure all the way from where the portal vein enters the liver. The veins penetrate the muscle wall of the rectum through very small openings. Hence, it can be realised how straining at stools, constipation etc. can cause dilatation of these veins i.e. haemorrhoids.

The Causes of Haemorrhoids are:
1. Man’s upright position
2. Heredity
3. Occupations that require severe muscular strain or prolonged standing or sitting in one position.

Aggravating Causes are: Constipation, diarrhoea, heart failure, portal hypertension, pregnancy, pelvic tumour, carcinoma of the rectum and anal infection.
Treatment: Different types of treatments practised are oral herbs, local applications of herbs, application of astringent ointments containing glycerine and tannic acid and ointments containing cortisone as an anti-inflammatory agent and local anaesthetics. Even excision has been practised for many years.

Dietary control has been advised since times immemorial. Probably, the idea was to avoid constipation which is an important causative factor.

The present clinical trial of Pilex tablets and ointment was undertaken to assess the role of these drugs in the treatment of piles.

Pharmacology and Mode of Action

Each Pilex tablet contains:

- Balsamodendron mukul 0.13 gm
- Melia azadirachta seeds 7 mg
- Shilajeet (Purified) 16 mg
- Exts. Phyllanthus emblica 16 mg
  - Terminalia chebula 16 mg
  - Berberis aristata 32 mg
  - Arisaema wallichianum 3 mg
  - Cassia fistula 16 mg
  - Bauhinia variegata 16 mg

Pilex is specially processed in the fresh juices and decoctions of the following plants: Commelina salicifolia, Mimosa pudica, Acorus calamus, Blumea lacera, Amorphophallus campanulatus and Caesalpinia bonducella.

Pilex ointment contains:

- Exts. Mimosa pudica 5%
- Vitex negundo 3%
- Calendula officinalis 2%
- Eclipta alba 3%
- Aesculus hippocastanum 2%
- Camphor 1.225%
- Base q.s. ad 100%

Prepared in Melia azadirachta, Ailanthus excelsa, Blumea balsamifera, Eclipta alba, Allium ascalonicum, Acorus calamus, Solanum nigrum etc.

Properties of Pilex: The following properties of Pilex have been noted in experimental animals.

1. It increases the tone of the venous walls.
2. It reduces the engorgement and turgidity of veins.
3. It has a styptic action, which controls bleeding.
4. It has anti-inflammatory properties.
5. It has a laxative action.
6. It relieves hepatic congestion and relieves portal pressure.
**Pilex Ointment**: Pilex ointment improves the tone of the veins. Its anti-inflammatory and antiseptic action reduces inflammation and expedites healing. Its counter-irritant action relieves congestion. Its local anaesthetic properties help to control the pain and pruritus. The styptic action of Pilex ointment checks bleeding.

**MATERIAL AND METHODS**
Patients attending the Surgical Department of Kasturba Hospital, B.H.E.L., Bhopal, were selected for the study. A detailed history was taken regarding age, sex, bowel habits, bleeding per rectum, pain in perianal region, itching, medicines used and other general symptoms. A thorough general examination was done to exclude any associated disease. Digital per rectum and proctoscopic examination were done and the size, position, colour and degree of piles were recorded every week for four weeks.

In a few patients coloured photographs were taken at weekly intervals to show the response to drugs in regard to size, bleeding, congestion and discharge.

**MANAGEMENT**
The patients were asked to take Pilex tablets two t.i.d. for fifteen days. Then the dose was reduced to two b.i.d. which was continued for a further period of four weeks. Pilex ointment was used externally before and after defaecation. Mild laxatives were given to patients who complained of severe constipation. Every patient was examined weekly during the course of therapy.

**OBSERVATIONS**
Distribution in various age groups:

<table>
<thead>
<tr>
<th>Age group in years</th>
<th>Males</th>
<th>Females</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>10-20</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>21-30</td>
<td>20</td>
<td>10</td>
<td>30</td>
</tr>
<tr>
<td>31-40</td>
<td>22</td>
<td>12</td>
<td>34</td>
</tr>
<tr>
<td>41-50</td>
<td>12</td>
<td>5</td>
<td>17</td>
</tr>
<tr>
<td>51-60</td>
<td>8</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>61-70</td>
<td>5</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td>Over 70</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>70</td>
<td>30</td>
<td>100</td>
</tr>
</tbody>
</table>

**PRESENTING SYMPTOMS**

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding per rectum</td>
<td>65</td>
</tr>
<tr>
<td>Constipation</td>
<td>50</td>
</tr>
<tr>
<td>Prolapse of piles</td>
<td>32</td>
</tr>
<tr>
<td>Itching</td>
<td>27</td>
</tr>
<tr>
<td>Mucous discharge</td>
<td>19</td>
</tr>
<tr>
<td>Perianal pain</td>
<td>10</td>
</tr>
<tr>
<td><strong>DEGREE OF PILES</strong></td>
<td></td>
</tr>
<tr>
<td>First-degree</td>
<td>35</td>
</tr>
<tr>
<td>Second-degree</td>
<td>52</td>
</tr>
<tr>
<td>Third-degree</td>
<td>13</td>
</tr>
</tbody>
</table>

One hundred cases of piles were treated with Pilex tablets and Pilex ointment. Of these 70 were males and 30 females. Response to the therapy was judged by the effect on presenting symptoms and by proctoscopic findings every week.

**Bleeding**: This was the most common symptom. Sixty five patients presented with bleeding per rectum. After four weeks of therapy the bleeding was completely checked in 50 cases and diminished in 15 cases.
**Constipation:** Fifty patients came with constipation. It was relieved after four weeks of therapy in 44 cases and was improved in 6 cases.

<table>
<thead>
<tr>
<th>Complaints</th>
<th>No. of cases</th>
<th>Completely checked</th>
<th>Diminished</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bleeding</td>
<td>65</td>
<td>50 (76.9%)</td>
<td>15 (23.9%)</td>
<td>–</td>
</tr>
<tr>
<td>Constipation</td>
<td>50</td>
<td>44 (88.0%)</td>
<td>6 (12.0%)</td>
<td>–</td>
</tr>
<tr>
<td>Prolapse</td>
<td>32</td>
<td>13 (40.6%)</td>
<td>10 (31.2%)</td>
<td>9 (28.1%)</td>
</tr>
<tr>
<td>Mucous discharge</td>
<td>19</td>
<td>19 (100.0%)</td>
<td>–</td>
<td>–</td>
</tr>
<tr>
<td>Itching</td>
<td>27</td>
<td>21 (77.7%)</td>
<td>3 (11.1%)</td>
<td>3 (11.1%)</td>
</tr>
<tr>
<td>Pain</td>
<td>10</td>
<td>8 (80.0%)</td>
<td>–</td>
<td>2 (20.0%)</td>
</tr>
</tbody>
</table>

**Prolapse:** This was another disconcerting symptom. Of the 32 cases prolapse was complicated by thrombosis and ulceration in 5 cases, perianal infection in 2 cases and fissure-in-ano in 1 case. There was definite improvement in the degree of prolapse. The pile masses had shrunk so that there was no prolapse in 13 cases. In another 10 cases, the prolapse had reduced to a great extent. There was, however, no change in 9 cases.

**Mucous Discharge:** In all the 19 cases who had this complaint the mucous discharge completely disappeared during the course of therapy.

**Itching:** There were 27 cases who complained of itching. Of these, 21 cases were completely relieved by the end of 4 weeks of treatment. The itching was diminished in 3 cases and there was no change in 3 cases.

**Pain:** Of the 10 cases of pain 8 responded very well to the treatment. There was, however, no change in 2 cases.

**Proctoscopic Findings**

**Size:** The size was reduced in quite a few cases. Upto the end of the second week, marked regression could be seen, and there was further regression at the end of the fourth week, although at a much slower rate.

**Congestion:** Again maximum decrease in congestion was noted at the end of the second week. There was further improvement after the end of four weeks.

**Discharge:** Decrease in discharge was seen in all the cases who had this complaint.

Piles completely disappeared in 10 cases. There was no change in proctoscopic finding in 25 cases. Although symptomatically they were much relieved.

**SUMMARY**

A clinical study was carried out in 100 cases of internal haemorrhoids who received Pilex tablets and ointment. The response to this therapy was found to be very encouraging. In first degree haemorrhoids the bleeding stopped in 76.9% cases, and reduced in 23.1% cases. At the end of the fourth week pain was completely relieved in 80% of cases. Similarly, constipation was relieved in 88% of cases and was markedly improved in 12% of the cases. There was no prolapse at the end of the fourth week of therapy in 40.6% of cases. Prolapse was markedly reduced in 31.2% of cases. Mucous discharge stopped in all the cases. Itching was relieved in 77.7% cases and reduced in 11.1% of cases. There was marked improvement in first and second degree haemorrhoids. The third degree piles also showed satisfactory improvement.
Our experience with Pilex tablets and ointment is very satisfactory and we feel that they should be more widely used in the conservative treatment of piles.

ACKNOWLEDGEMENTS
We are very grateful to Major General K.V. Pillai, Chief Medical Officer, Kasturba Hospital, Bhopal for allowing us to conduct this trial.

We are thankful to The Himalaya Drug Company for the generous supply of Pilex tablets and ointment and for other help.

REFERENCES
4. *Gray’s Anatomy Descriptive and Applied*.