CLINICAL EVALUATION OF SOME HERBAL MEDICINE FOR AMOEBIASIS

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ABSTRACT:

Background: Amoebiasis is a worldwide disease, particularly common in tropical countries and places where public hygiene and sanitation are poor. Amoebic infection is caused by an organism, Entamoeba histolytica (E.H.) that usually spreads through contaminated food and water. Since the causative organism of amoebiasis derives its nutrition from the normal bacterial flora of the large intestine, the latter is the chief site of infection. Aim of the study is to decrease the prevalence of Amoebic Dysentery in the community by trusted and cost-effective herbal medicinal preparation. Clinical evaluation of amoebiasis and its treatment was undertaken to evaluate the therapeutic efficacy of herbal coded medicine Amoebin Cap along with a comparative study of another Herbal Medicine Endemali, an Allopathic Medicine Entamizole DS and placebo.

Method: A randomized, clinical, comparative study has been conducted between the formulated herbal medicine Amoebin Cap, allopathic medicine Entamizole DS, herbal proprietary product Endemali and placebo to provide clinically evidence based assessments. Amoebin Cap comprises of herbs such as Phyllanthus emblica, Aegle marmelos, Holarrhena antidysenterica and Myrtus communis. The clinical evaluation involved quite a number of patients living in Karachi around 202 patients selected for the final diagnosis and treatment of amoebiasis. The clinical trial was conducted to assess the drugs and the details of which are given along with tables with its graphic representations. The number of patients assigned to test group that is Amoebin Cap were 80, while in control group 63 patients were registered to Entamizole DS and 50 patients for Endemali along with this 9 patients were kept on placebo.

Results: The data was collected in the years from 2001-2004. There were total 202 patients, the frequency of male patients were 127 (percentage of male 62.9%) while, 75 of female patients (percentage of female 37.1%) were enrolled into the study. Using a Chi-Square Test and Fisher Exact Test statistical analyses were made. All patients which were treated with Amoebin Cap showed improvement. Out of 63 patients who were treated by Entamizole DS 58 showed improvement and five did not. After applying the test of significance there was significant difference between these two drugs. Fisher Exact Test was applied and p-value was calculated as 0.015 while comparing Amoebin cap with Endemali 50 patients treated with an herbal drug Endemali. Results revealed that all patients, which were treated with Amoebin Cap, showed improvement, and out of 50 patients who were treated by Endemali 30 showed improvement and twenty did not. Conclusion: After applying the test of significance there was highly significant difference between these two drugs with Chi-Square Test was deduced (Yates correct) 34.81 and p-value was found to be 0.000.

BACKGROUND

Amoebiasis is a type of gastroenteritis caused by a protozoan parasite, Entamoeba histolytica, which infects the bowel and resides in the large bowel, amoebae occasionally penetrate the intestinal mucosa and may disseminate to other organs. The
factors that trigger invasion are unknown. Amoebiasis can affect anyone, however, the disease mostly occurs in young to middle aged adults. Amoebiasis is generally associated with people living in areas of poor sanitation and is a common cause of diarrhea among travelers to developing countries (Ansari et al., 1998).

The most common symptoms of amoebiasis are diarrhea (which may contain blood), stomach cramps and fever. Rarely, amoebiasis can cause an abscess (infection) in the liver. After infection, it may take a few days, several months or even years before the person become ill but it is usually about two or four weeks. To trace the cause of the illness, it is necessary to know what have been eaten and drank and where has been traveled in the weeks before the illness. *Entamoeba histolytica* parasites are only found in humans. Amoebiasis occurs when *Entamoeba histolytica* parasites are taken in by mouth and the most common way this happens is by person-to-person spread (Guerrant et al., 1990).

There are a large number of species of amoebae which parasitize the human intestinal tract, of these *Entamoeba histolytica* is the only species found to be associated with intestinal disease. Although many people harbor this organism world wide, only about 10% develop clinically invasive disease thus the parasite has been shown to present as two very differing clinical presentations (Snell et al.).

**METHODS**

The therapeutic evaluations of these medicines were conducted on 202 clinically and biochemically diagnosed cases of amoebic dysentery at Shifa-ul-Mulk Memorial Hospital, for Eastern Medicine, Hamdard University. The patients were registered from the general O.P.D. and hospitalized to the clinical Research ward of the Hospital. All the patients selected for the study, were thoroughly examined and clinical history was recorded.

Out of total 202 patients treated for amoebiasis, 80 patients were treated from herbal formulated drug Amoebin Cap and 63 patients treated with an allopatic medicine Entamizole DS. All patients which were treated with Amoebin Cap showed improvement. Out of 63 patients who were treated by Entamizole DS, 58 showed improvements and five did not show any improvement. After applying the test of significance there was significant difference between these two drugs with Fisher Exact Test was applied and p-value was calculated as 0.015 as shown in Table-1.

**Table-1**

Comparison of Amoebin Cap with Entamizole DS with regards to improvement

<table>
<thead>
<tr>
<th>Improvement</th>
<th>Drugs</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amoebin Cap</td>
<td>Entamizole DS</td>
</tr>
<tr>
<td>Improved</td>
<td>80</td>
<td>58</td>
</tr>
<tr>
<td>Not Improved</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>63</td>
</tr>
</tbody>
</table>

Out of 130 patients treated for Amoebiasis 80 patients were treated from herbal formulated drug Amoebin Cap and 50 patients treated with an herbal drug Endemali. All patients which were treated with Amoebin Cap showed improvement. Out of 50 patients who were treated by Endemali 30 showed improvement and twenty did not.

Fig. 1: Comparative efficacy of Amoebin Cap with Endemali.
applying the test of significance there was highly significant difference between these two drugs with Chi-Square Test was deduced (Yates correct) 34.81 and p-value was found to be p=0.000 as shown in Table-2.

Table-2
Comparison of Amoebin Cap with Endemali with regards to improvement

<table>
<thead>
<tr>
<th>Improvement Scale</th>
<th>Drugs</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Amoebin Cap</td>
<td>Endemali</td>
</tr>
<tr>
<td>Improved</td>
<td>80</td>
<td>30</td>
</tr>
<tr>
<td>Not Improved</td>
<td>0</td>
<td>20</td>
</tr>
<tr>
<td>Total</td>
<td>80</td>
<td>50</td>
</tr>
</tbody>
</table>

Fig. 2: Comparative efficacy of Amoebin Cap with Endemali

The criteria for assessment of therapeutic evaluation of Amoebin Cap, Entamizole DS, and Endemali based on improvement in presenting complaints, sign and symptoms. The comparative clinical data on improvement in sign and symptoms of the patients treated with Amoebin cap, Entamizole DS and Endemali, Amoebin Cap showed complete improvement in watery stool 16 out of 21, mucus mixed with blood 39/43, feeling of evacuation 3/4, Stool with mucus 67/75, stool with blood 42/46, intermittent diarrhea and constipation 39/31, abdominal cramps 55/63, right hypochondrial pain 9/10, weight loss 3/3, nausea and vomiting 8/9, diarrhea with mucus 67/75, flatulence 22/25, abdominal tenderness 2/3, dehydration 46/48, whereas Entamizole DS showed improvement in watery stool 10 out of 12, mucus mixed with blood 27/37, feeling of evacuation 6/8, Stool with mucus 42/57, stool with blood 28/38, intermittent diarrhea and constipation 18/26, abdominal cramps 42/57, right hypochondrial pain 1/1, weight loss 4/4, nausea and vomiting 12/17, diarrhea with mucus 42/57, flatulence 21/25, abdominal tenderness 9/11, dehydration 21/31, and Endemali showed complete improvement in watery stool 6 out of 20, mucus mixed with blood 9/33, stool with mucus 11/41, stool with blood 9/34, intermittent diarrhea and constipation 8/25, abdominal cramps 9/41, right hypochondrial pain 1/5, weight loss 0/5, nausea and vomiting 9/32, diarrhea with mucus 11/41, flatulence 5/15, abdominal tenderness 0/6, dehydration 11/31.

RESULTS

Statistical analysis were made by using a Chi-Square Test and Fisher Exact Test. Out of 202 patients treated for amoebiasis, 80 patients were treated from herbal formulated drug Amoebin Cap and 63 patients treated with an allopathic medicine Entamizole DS. All patients which were treated with Amoebin Cap showed improvement. Out of 63 patients who were treated by Entamizole DS 58 showed improvement and five did not. After applying the test of significance there was significant difference between these two drugs with Fisher Exact Test was applied and p-value was calculated as 0.015 while comparing Amoebin cap with Endemali 50 patients treated with an herbal drug Endemali. Results revealed that all patients which were treated with Amoebin Cap showed improvement, and out of 50 patients who were treated by Endemali 30 showed improvement and twenty did not. After applying the test of significance there was highly significant difference between these two drugs with Chi-Square Test was deduced (Yates correct) 34.81 and p-value was found to be 0.000.
CONCLUSION

After comparing the results from this study the conclusion was established as: Null hypothesis was rejected which was that, the herbal coded formulation *Amoebin Cap* is of the same value as herbal medicine *Endemali* and allopathic medicine *Entamizole DS* and there is no difference between these three medicines and are evenly effectual for the treatment of amoebiasis.

REFERENCES

