CLINICAL RESEARCH

Drug oriented Clinical Research on Amoebic dysentery

Abstract

Background: Wide prevalence of Amoebiasis in tribal areas formed the basis of selection of amoebic dysentery as a research problem.

Aims: The objective was to evaluate the efficacy of a group of partially proved drugs/or lesser known drugs for Amoebic dysentery.

Setting and design: This study was undertaken at *Dimapur* (1985), *Itanagar, Dandeli, Agartala* (1988), **Jeypore, Khongjom** (1990), *Gangtok* (1991) and concluded in March 2003.

Materials and Methods: Clinically diagnosed cases of Amoebic dysentery were selected out of patients reporting in general O.P.D. for treatment. The prescription was based on the symptom similarity of the disease picture presented by the patients with that of the known pathogenetic action of the assigned drugs. Results- *Cynodon dactylon, Trombidium, Atista indica, Ficus indica, Emetine, Holarrhena antidysenterica, Raphanus, Leptandra, Alstonia constricta* in variable potencies have been found effective in controlling/preventing Amoebic dysentery. However *Asclepias tuberosa, Ambrosia, Helleborus* were found to be less indicated and the number of cases in whom they were prescribed is too less to draw definitive conclusion. 1 drug, Silphium was not found effective in treatment of patients.

Conclusion: Effectiveness of the homoeopathic drugs used empirically and rarely is not properly documented. The results testify their positive role in Amoebic dysentery but needs further confirmation on large trial with strict guidelines of the protocol including laboratory parameters.

Introduction

Most common type of amoebic infection is asymptomatic cyst passage. Symptomatic amoebic colitis develops 2 to 6 weeks after the ingestion of infectious cysts. Lower abdominal pain and mild diarrhoea develop gradually and are followed by malaise, weight loss, and diffuse lower abdominal or back pain. Patients with full-blown dysentery may pass 10 to 12 stools per day. The stools contain little fecal material and consist mainly of blood and mucus. In contrast to those with bacterial diarrhoea, fewer than 40% of patients with Amoebic Dysentery are febrile. Virtually all patients have **heme-positive** stools.

The literature of Homoeopathy and the Materia Medica report of usefulness of Homoeopathic medicines in conditions simulating Amoebic Dysentery. However, no pathological confirmation is cited in the Materia Medicas. The council decided to conduct a clinical trial to ascertain the role of Homoeopathy in the management of Amoebic Dysentery by virtue of application of lesser-known drugs.

In the initial phase the tribal pockets surveyed for disease prevalence etc. Based on the initial findings Amoebic Dysentery was found to be widely prevalent in some of these areas.

Since tribal population was a virgin population in terms of health care facilities & homoeopathic therapeutic action, a few lesser-known homoeopathic drugs were selected to be studied on these groups so as to extract their maximum therapeutic potential.

Objectives

The objective of the study was to evaluate the efficacy of partially proved drugs/or lesser known drugs for Amoebic dysentery viz., Alstonia constricta, Ambrosia, Asclepias tuberosa, Atista indica, Cynodon dactylon, Emetine, Ficus indica, Leptandra, Silphium, Trombidium, Holarrhena antidysenterica, Raphanus, Helleborus, whose symptomatic data available in the literature was found to be insufficient.

Materials and Methods

Literature survey was done to collect information (whatever available) on rare and lesser-known drugs (mostly of indigenous origin) showing signs and

symptoms similar to Amoebic dysentery or having traditional use for diarrhoea and dysentery. Out of these Alstonia constricta, Ambrosia, Asclepias tuberosa, Atista indica, Cynodon dactylon, Emetine, Ficus indica, Holarrhena antidysenterica, Helleborus, Leptandra, Raphanus, Silphium, Trombidium, Xanthoxylum, Zincum sulphuricum, were approved and short listed by Scientific Advisory Committee. Their indications were compiled and sent to the concerned Clinical Research Units for further verification as well as collection of additional symptoms (clinical symptoms), if any.

Centres of study

This study was started in the year 1985 (Dimapur), 1988 (Itanagar, Dandeli, Agartala), 1990 (Jeypore, Khongjom), 1991 (Gangtok) and concluded in March 2003.

Basic design

Clinical trial of selected Homoeopathic medicines on tribal population based on symptom similarity.

Sample size fixed

7525 cases

Study population

Patients reporting in unit's O.P.D.

Inclusion criteria

Clinically diagnosed cases with following symptoms/ signs were included for study:

- Frequent stool
- Stools with mucus and streaks of blood, offensive
- Tenesmus associated with stool
- Tenderness along the line of the colon
- Pyrexia may or may not be there

Exclusion criteria

All such cases of grave nature and requiring hospitalization were excluded from study

The details of the Symptomatology presented in the research subject were recorded in a case recording proforma based on the principles of homoeopathic philosophy.

Assessment criteria

1. Improvement was assessed on the basis of following criteria:
   - Reduction in frequency of stools
   - Improvement in pain and tenesmus in abdomen
   - Disappearance of blood & mucus in stool
   - Relief in pyrexia, if present.
2. No improvement: When no relief is observed in symptoms and signs of Amoebic Dysentery after taking medicine for 4-7 days.

Scope and limitation

With the primary objective of this pilot research study to ascertain the therapeutic efficacy of lesser-known homoeopathic drugs in amoebic dysentery, the study was initiated in the tribal populations of the country. At the same time it served to provide organized medical care to the tribals. Although definitive laboratory facilities were absent and the assessment was based only on subjective and objective symptomatic parameters, yet this study has paved the way for further organized and statistically viable studies.

Source of drugs/dosage

The drugs used in the study were procured from authorized homoeopathic pharmacies. The drugs were prescribed in each individual case on the basis of symptom similarity. The Potency and dosage was selected as per homoeopathic philosophy taking into consideration the presentation of the case.

Results

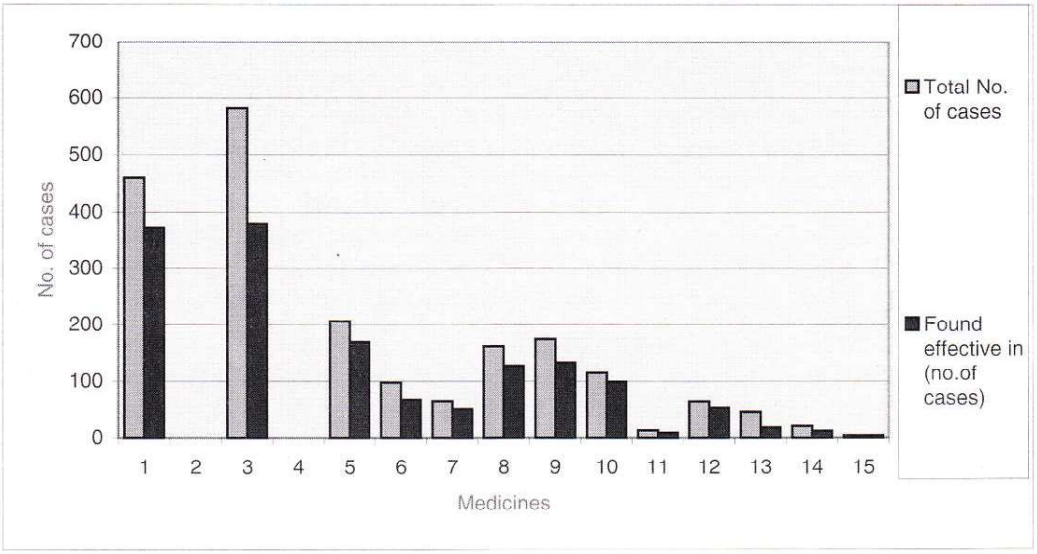
Target achieved: 6179 number of cases were studied.

Number of cases found effective in – 2197

The drugs found most effective in controlling Amoebic dysentery were Alstonia constricta, Atista indica, Cynodon dactylon Emetine,, Ficus indica, Holarrhena antidysenterica, Leptandra, Raphanus and Trombidium.

Results with regard to individual drugs

S.No.	*Name of the Drug*	*Total No. of cases administered*	*Found effective in (no.of cases)*
1.	Alstonia constricta	98	68
2.	Ambrosia	21	12
3.	Asclepia	13	09
4.	Atista indica	206	170
5.	Cynodon dactylon	461	373
6.	Emetine	66	52
7.	Ficus indica	115	99
8.	Helleborus	04	04
9.	Holarrhena antidysenterica	162	128
10.	Leptandra	175	133
11.	Raphanus	65	54
12.	Silphium	47	18
13.	Trombidium	582	380



Signs/symptoms ameliorated during study

Atista indica 30,200:

Frequent eructations after meals.

Throbbing pain at the pit of the stomach.

Colicky pain around the navel.

Tenesmus & drawing pain at the anal region.

Stool, pale earthy in colour.

Flatulence and heaviness of abdomen, better by eructation.

Trombidium 30,200:

Dysentery aggravated by food and drink.

Pain in rectum before & after stool.

Griping pain and tenderness in abdomen.

Stool loose watery mixed with blood and mucus.

Burning pain in anus.

Cynodon dactylon 30,200:

Flatulence with distension of abdomen.

Pain and tenesmus aggravated before stool.

Stool mixed with blood and mucus.

Loss of appetite with dryness of tongue.

Thirst for large quantity of water at long interval.

Emetine 30,200:

Dysentery.

Abdominal pain, nausea.

Colicky pain around umbilicus.

Slimy, mucoid stool, with frequent urging.

Holarrhena antidysenterica 6,30,200:

Bloody mucus with stool.

Colicky pain around the umbilicus.

Colicky pain associated with stool.

Extreme weakness.

Raphanus 30,200:

Itching at anal region.

Loss of appetite, vomiting.

Retching, griping about naval.

Frothy, profuse brown stool.

Ficus Indica 30, 200:

Dysentery with piles stool mixed with pure red blood.

Bleeding before evacuation.

Dysentery associated with great urging, colic and tenesmus.

Alstonia constricta 30, 200:

Diarrhoea after eating

< by fatty, fried food

Colic before stools.

Nausea and vomiting

Stool with whitish mucus.

Stool loose, watery, yellowish.

Loss of appetite.

Leptandra 30, 200:

Great distress in stomach and intestines.

Black tarry stool.

Stool profuse, black fetid with pain at umbilicus.

< after stool.

Disucussion

Nine (9) out of 15 drugs were found effective in preventing/controlling the disease in the areas where Amoebic dysentery is widely prevalent. these drugs are (i.e. Cynodon dactylon 30, 200, Trombidium 30, 200, Atista indica 30, 200, Ficus indica 30, 200, Emetine30, 200, Holarrhena antidysenterica 6, 30, 200, Raphanus 30, 200, Alstonia constricta 30, 200, 30, 200.) However 3 drugs viz. Asclepias tuberosa, Ambrosia, Helleborus were found to be less indicated with few cases only. One drug, Silphium was not found effective.

The symptoms of the research subjects which were ameliorated were compiled. These symptoms were found to corroborate with the drug provings and clinically verified symptoms as given in the Materia medicas. It confirms the pathogenesis of these lesser known drugs and their therapeutic potential.

Due to various constraints at Clinical Research Units (Tribal), efficacy of the drugs could not be corroborated with laboratory findings like change in leucocytes count, post treatment negativity of Entamoeba histolytica cysts etc.

Conclusion

Effectiveness of the homoeopathic drugs used empirically and rarely is obscure. The results testify their role in Amoebic dysentery but need further confirmation on large trial with strict guidelines of the protocol including laboratory parameters. There is need to evaluate detailed pathogenesis of lesser-known drugs for their wider use.

Acknowledgements

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Reference

Concluding reports of Tribal Research Units at Dandeli (Karnataka), Dimapur (Nagaland), Itanagar (Arunachal Pradesh), Jeypore (Orissa), Khongjom (Manipur), Gangtok (Sikkim) and Agartala (Tripura).