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Human Fascioliasis in Northern Iran: Clinical Features and Treatment

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ABSTRACT

Background: Fascioliasis is a zoonotic parasitic disease, caused by the liver fluke *Fasciola* spp.. We aimed to investigate the clinical signs of human fasciolosis before and after treatment with triclabendazole. The drug efficacy and its side effects were also assessed.
Methods: Fifty confirmed fasciolosis patients, 15 males and 35 females, were chosen for parasitological and serological examinations pre-therapy as well as 1- and 6-months post-therapy. For stool examination formalin-ether and modified Telemann methods and for *Fasciola* antibody detection Elisa technique was applied.
Results: Overall, 100% and 18% of patients had positive ELISA and stool exams before treatment, respectively. The most frequent sign was abdominal pain (96%). The cure rate of the patient based only on stool examination was 100% after consumption of single dose of triclabendazole (10 mg/kg of body weight). Transient abdominal pain (mild and moderate) was the most frequent adverse sign following treatment with triclabendazole.
Conclusion: A single dose of triclabendazole (10 mg/kg) proved to be a successful therapeutic intervention, effectively eliminating the infection with manageable side effects.

Keywords: Clinical feature, Human fascioliasis, Triclabendazole, Iran

Introduction

Fascioliasis, a parasitic infection caused by the trematode *Fasciola hepatica*, is a zoonotic disease of significant economic importance in domestic livestock, particularly cattle and sheep. Human infection, though accidental, poses an emerging public health problem globally (1). Humans become incidental hosts upon ingestion of the infective metacercarial stage, typically

through the consumption of contaminated aquatic plants such as watercress (2).

The geographical distribution of human fascioliasis is broad, with cases reported in over 60 countries, spanning regions of Europe, the Americas, Asia, and Africa (1). Prevalence estimates vary considerably, reflecting differences in diagnostic methods and reporting; figures range from approximately 2.4 million to 17 million people infected worldwide (3, 4). The public health impact has become increasingly apparent over the past two decades. A notable example is the 1989 outbreak in Iran's Guilan province (Caspian Sea littoral), which affected more than 10,000 individuals, highlighting the epidemic potential of this zoonosis (5).

The treatment of human fascioliasis has historically been challenging. Several drugs, including dehydroemetine, bithionol, and praziquantel, have been used with limited success. Their utility is constrained by substantial side-effects, such as the cardiotoxicity associated with dehydroemetine, and/or incomplete efficacy against the tissue-migratory stages of the parasite (6-8). Notably, *F. hepatica* demonstrates innate resistance to praziquantel, a cornerstone of other trematode treatments (9).

Triclabendazole, a member of the benzimidazole family of anthelmintics, has revolutionized the management of fascioliasis. While sharing a core benzimidazole structure, triclabendazole is pharmacologically unique due to its chlorinated benzene ring and lack of a carbamate group (10). This structural distinction underpins its superior efficacy against both immature and adult liver flukes, making it the current drug of choice for all phases of the disease—acute, invasive, and chronic (11). The anthelmintic action of benzimidazoles, including triclabendazole, is primarily attributed to the binding and disruption of β-tubulin polymerization, which inhibits the formation of microtubules. This leads to impaired nutrient uptake and cellular integrity in the tegument of the fluke (12). The WHO recommends a regimen of two doses of 10 mg/kg body weight for human treatment (13).

Given its pivotal role in therapy, ongoing evaluation of triclabendazole's performance in clinical settings remains essential. We aimed to describe the clinical profile of human fascioliasis and to evaluate the efficacy and tolerability of triclabendazole among patients in Gilan Province, Northern Iran.

Materials and Methods

Patients

Fifty patients (15 men and 35 women) with mean age of 38 years from Anzali City in the North of Iran, in the established phase of fascioliasis were enrolled in this study. All had a negative history concerning treatment of the liver fluke in the month preceding this study.

Ethics: The study approved by Tarbiat Modares University (Tehran, Iran) Ethics Committee. Informed consent to participate in the clinical trial was obtained from all.

Drug assessment

All the patients received 10 mg/kg of triclabendazole either single or double doses (9). The second dose was given to the patients who were not responding to the single dose.

Assessment of efficacy of drug

The cure rate was assessed after use of triclabendazole by two methods, which included, the absence of eggs from stools & the relief of clinical signs.

Clinical and laboratory examinations

Upon three steps of follow up (day 0, one month and six months after treatment), all patients were subjected to clinical examination; stool examination (formalin-ether and Modified Telemann techniques) and ELISA test for fascioliasis using ELISA kit (Pishtaz Teb Diagnostics, Iran). Tolerability of triclabendazole was assessed clinically.

Statistical analysis

Qualitative descriptive tests were used to calculate the frequency and percentage of infection, and chi-square and Fisher's exact tests were used to compare the infection rate in different groups. All statistical analyses were performed using SPSS version 23 software (IBM Corp., Armonk, NY, USA). The *P* value less than 0.05 was considered significant differences.

Results

The clinical signs of the 50 patients included in study are presented in Table 1. The frequency of abdominal pain was higher than the other complaints followed by muscular pain, skin itch, right hypochondrial pain and urticaria. The frequencies of nausea, vomiting, headache, diarrhea, sweating, hepatomegaly and splenomegaly between men and women were statistically significant ($P<0.05$).

Table 1: Symptoms and abdominal signs in 50 patients infected with fascioliasis

Clinical signs	Male		Female		Total	
	No.	%	No.	%	No.	%
Abdominal pain	14	93	34	97	48	96
Muscular pain	12	80	31	87	43	86
Skin itch	7	47	19	54	26	52
Right hypochondrial pain	7	47	16	46	23	46
Urticaria	7	47	15	43	22	44
Fever	3	20	9	26	12	24
Nausea and vomiting	1	7	9	26	10	20
Headache	2	13	7	20	9	18
Diarrhea	5	33	4	11	9	18
Sweating	1	7	7	20	8	16
Hepatomegaly	0	0	7	20	7	14
Cough	2	13	4	11	6	12
Splenomegaly	0	0	2	6	2	4

After the first day of treatment, clinical examination revealed a mild increase in right hypochondrial pain, abdominal colic, fatigue, skin itch and urticaria. However, the following examinations, the intensity of colic and the frequency of complaints decreased gradually (Table 2).

Table 2: The frequency and percentage of side effects of triclabendazole in the patients

Side effects	No.	%
Abdominal pain		
Light	11	22
Mild	5	10
Fatigue		
Light	12	24
Severe	2	4
Skin itch	7	14
Urticaria	3	6
Without any adverse effects	27	54

The cure rate in the patients receiving single dose of triclabendazole was 100% based on stool examination following administration of single dose (Table 3).

Table 3: Cure rates of the patients following consumption of single or double doses of triclabendazole evaluated by stool examination

Patients	Cure rate (Negative stool exam)	
	No.	%
Male	15	100
Female	35	100
Total	50	100

Discussion

In 1989 an outbreak of human infestation was reported in more than 10,000 cases in Gilan Province, Iran (1, 5) Although the source of the infection is still not identified, but an aromatic vegetable which is locally called Khalvash, was proposed to be an important source. Khalvash is kind of wild vegetable that grows in Anzali pool and people use it freshly with their meal. The human infestation can be acquired by ingestion of contaminated vegetable or watercress. In the present study, fifty consenting patients were selected from Anzali city in Gilan Province. Their clinical picture and the results of laboratory investigations, prior to treatment, matched with those reported in studies reviewed by Chen and Mott and study of Farag et al. (14, 15).

In human fascioliasis four clinical periods can be distinguished: incubation phase, invasive or acute phase, latent phase and obstructive or chronic phase. In the acute phase, the main symptoms are fever, pain in the right hypochondrium and abnormal laboratory findings. In the chronic phase the clinical picture is attenuated and easily confused with other diseases. The classic pattern include vague gastrointestinal complaints, pain in the right hypochondrium or epigastrium, cholecystitis, cholangitis and bile duct or gall bladder stones (16).

Triclabendazole has been reported as very effective drug against both acute and chronic forms of human fascioliasis (17-25). The recommended dose is two separate regimens of 10 mg of the drug per kg body weight (16). A cure rate of 79.2% at a single oral dose (10 mg/kg body weight) and 100% after a second administration was reported by Ape et al. (17). The cure rates were also reported 78% and 92% in the patients receiving single dose and 100% after second dose administration in El Karasky et al. and Milan et al. studies respectively (18, 19). Cure rates of 79 to 100% have also been reported by other researchers in which a single oral dose or repeated doses totally 10 and 20 mg/kg body weight were used (7, 20-24). Some of these studies were performed during the acute phase of infection and relied on serology tests as the parameter for assessment of the cure (17). In some other studies, the absence of eggs during stool examination was selected as the main indicator for parasitological cure (20-24).

In the present study, if we assume the cure rate based on stool examination only, the results could be considered high even after single dose of triclabendazole. However, by taking into account all two parameters like the stool examination and clinical pictures as the indicators for the cure, the cure rate amounted to 100% after a month of treatment. In fact, during stool exami-

nations for diagnosis of human fascioliasis several important points should be considered. Diagnosis of the disease in the period of immature flukes or during acute phase by stool examination is not reliable. In contrast, immunological techniques like ELISA test are applicable during all phases of the disease and are more reliable methods (16).

The tolerance of triclabendazole was considered excellent in these patients. Side effects were in the form of brief episodes of upper abdominal pain. These effects may be due to the paralysis and/or death of the flukes resulting in the release of antigens or toxic products and the partial blockage of the bile ducts. Similar findings have been reported in various preliminary studies where the drug has been reported to decrease parasite motility, however, the exact mode of action of triclabendazole is unknown (19).

Triclabendazole has been reported to be a non-mutagenic and non-teratogenic drug (17). These factors together with its effectiveness and tolerability could allow the physicians to recommend triclabendazole for human use against fasciolosis.

Conclusion

Triclabendazole is a highly effective treatment for human fascioliasis, achieving a 100% parasitological cure rate based on stool examination six months post-treatment. Clinical assessment revealed abdominal pain as the most prevalent pre-treatment symptom (96%). While triclabendazole was well-tolerated overall, the most common post-treatment adverse effect was transient abdominal pain, typically mild to moderate in severity. The notable discrepancy between serological (ELISA, 100% positive) and parasitological (stool exam, 18% positive) diagnostic results pre-treatment highlights the value of combining both methods for accurate diagnosis and subsequent confirmation of cure.

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Conflicts of interest

There is no conflicts of interest.

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