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ASSESSMENT OF THE EFFECTS OF TREATMENT OF 2 ALBENDAZOLE AND PRAZIQUANTEL PROGRAMS IN PATIENTS WITH PORK TAPEWORM LARVAL DISEASE INFECTION IN THE BRAIN (2017 – 2020)

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ABSTRACT

The study treated 120 patients infected with tapeworm larvae with albendazole and praziquantel (60 patients each group), the results showed that:

- Clinical treatment effect: After 6 months of treatment, the main clinical symptoms such as headache, convulsions, myoclonus... were significantly improved, only 25% in the albendazole and 21 treatment groups. 7% of the praziquantel group still had headaches; However, the level of headache decreased markedly. There were no more patients with seizures, the number of myoclonus accounted for 5.0% in the albendazole group and 3.3% in the praziquantel group.

- Clinical efficacy after treatment: the percentage of patients who had no clinical symptoms of albendazole was 65% and praziquantel was 73.3%. The proportion of patients with clinical symptom reduction in the albendazol regimen 35% and praziquantel 26.7%, The therapeutic effect of albendazole dose 20mg/kg/24 hours x 20 days x 3 times and praziquantel dose 30mg/kg/24 hours x 15 days x 3 episodes, 1 month apart in patients infected with brain tapeworm larvae are similar.

- Effective treatment on cysts as determined by MRI:

+ Patients with a small number of cysts in the brain (1 cyst) had a high rate of cyst clearance of 66.6% with albendazole and 75% with praziquantel, patients with many cysts were less effective.

+ All cysts in stage 1 and 2 are responding well to treatment, after treatment there are no cysts in stage 1 and 2 or cysts have changed to stage 3, 4, 5 with both albendazole and praziquantel .

+ The percentage of patients who lost their cysts after treatment with albendazole was 51.7%, and praziquantel was 66.7%. The rate of patients with cyst reduction after treatment with albendazole was 48.3% and praziquantel was 31.7%.

- General therapeutic effect:

After 6 months of treatment, clinical results and MRI images with albendazole regimen were 38.3%, disease reduction was 61.7%. With the praziquantel regimen: the cure rate was 53.3%, the disease reduction was 45%. The overall therapeutic effect of albendazole and praziquantel is similar.

KEYWORDS: *albendazole; praziquantel; Pork tapeworm larval disease.*

1. QUESTION

Pork tapeworm larval disease is an infection caused by Pork tapeworm larval disease. Taenia solium cysts caused by eating fluke eggs. Foodborne illness is closely related to eating habits (eating raw and undercooked pork) or poor hygiene (poor management and handling of feces). The disease is endemic in many countries with difficult economic conditions and poor sanitation, such as in Africa, Central America, and South America, especially in some Asian countries such as India, China and Vietnam. When people ingest pork tapeworm eggs, the eggs enter the intestines to develop into larvae. Larvae penetrate through the intestinal wall according to the circulatory system to move to the brain, eyes, heart, skeletal muscle ... and cause different symptoms depending on the parasite's location. Pork tapeworm larval disease in the brain can lead to serious symptoms such as convulsions, seizures, paralysis…

In the United States, each year there are more than 1800 hospital admissions because of the absence of tapeworm larvae, the number of hospitalizations as well as the medical costs for pork tapeworm larvae are not more than all neglected tropical cases plus. Again. In China, tapeworm larvae do not account for 60-90% of epileptic patients. In Vietnam, up to now, at least 55 provinces have detected cases of tapeworm larvae, concentrated in the provinces of Bac Ninh, Bac Giang, Lai Chau, Son La.... According to statistics of the Institute of Malaria - Parasites - Insects, from 2015-2020, each year, there are about 300 cases of untreated swine tapeworm larvae at Dang Van Ngu hospital.

The clinical symptoms of tapeworm disease in the brain as well as the diagnostic, therapeutic and prognostic criteria for the disease are complex, depending on the stage, location of parasites, number and size of cysts. Tapeworm larvae as well as the patient's immune response. Criteria for the diagnosis of tapeworm larvae in the brain include clinical symptoms, laboratory tests such as histopathology, serology, and imaging. Histopathological examination or biopsy of the tapeworm cyst is usually not or rarely done. Immune serology tests in larval disease, including test for detecting antigens and antibodies, are not sensitive, cross-positive with some other parasites such as strongyloides, schistosomiasis. In tapeworm disease, imaging plays an extremely important role. The diagnosis of tapeworm in the brain has been greatly improved with the advent of computed tomography (CT) and magnetic resonance imaging (MRI). These techniques clearly show the number and location of lesions, the stage as well as the invasion and extent of the body's inflammatory response to the parasite. MRI provides better image detection and definition. However, the cost of MRI is high and its sensitivity for detecting calcified lesions is poorer than that of CT.

In terms of treatment, since the 1980s, praziquantel and albendazole have been widely used in the treatment of brain tapeworm larvae and achieved satisfactory therapeutic effects. These two drugs also have many studies, but the dosage and treatment course need to be continuously researched in many countries to achieve optimal effectiveness. Many studies have not clearly shown the mechanism of action of the drug, the response of the body in general, especially the brain, so treatment is still a dilemma. Monitoring and evaluating the effectiveness of drug interventions in treatment is necessary, step by step perfecting treatment regimens at specialized treatment facilities and hospitals throughout the country is an objective and practical requirement. However, to evaluate the therapeutic effect of drugs by MRI images in Vietnam, there are few authors mentioned. Stemming from the above practical and scientific requirements, we conducted a research on the topic with the aim: To evaluate the effectiveness of treatment with 2 regimens of albendazole and praziquantel on patients infected with tapeworm larvae in the brain in 2017 - 2020.

2. RESEARCH SUBJECTS AND METHODS

2.1. Subject, location, time of research

- Subjects of the study: The patient was diagnosed with brain tapeworm larvae.

+ Criteria for selecting research patients: Age: Patients > 10 years old; Was diagnosed with tapeworm larvae infection in the brain at the Department of Specialized Examination and hospitalized.

+ Exclusion criteria: Patients who did not agree to participate in the study. Patients are being monitored and treated for other infections, blood diseases, pregnant women, lactating women, liver diseases, chronic kidney diseases, schizophrenia...

- Research location:

+ Dang Van Ngu Hospital, National Institute of Malaria - Parasitology - Entomology. As the leading specialist in the treatment of parasitic diseases, especially the brain tapeworm larvae. Annually, about 200-300 turns of brain tapeworm larvae are treated as inpatients.

+ Imaging Center 178 Thai Ha, under the General Hospital of Agriculture. Established in 2002 and a partner of the specialized medical examination department, the National Institute of Malaria - Parasitology - Entomology has been around since its establishment. Annually, the center conducts CT/MRI scan of the brain to diagnose patients with brain infection in 150-200 cases before and after treatment.

- Research period: From January 2017 to December 2020.

2.2. Research Methods

**** Study design:*** The study was designed by the method of evaluating the treatment effectiveness of 2 regimens praziquantel and albendazole (with equivalent therapeutic effect).

**** Sample size and sampling method***

- The sample size is calculated according to the formula to calculate the sample size of the results of the treatment of 2 regimens with equivalent effectiveness (non-inferiority). In this case, the therapeutic efficacy of albendazole is 90% and assuming the effectiveness of praziquantel is 95% or less than 7% (d=7%), then the two drugs are considered to be equivalent. With $\alpha = 0.05$ and $1-\beta = 80\%$ (force of sample) the sample will be 60 patients, so $n1 = n2 = 60$ patients for each group.

- The sample size is calculated based on the method of calculating the sample size according to the force of the sample. in the site: http://www.seaedenvelope.com/power_binary_noninferior.php

Thus, group 1 received albendazole 60 patients and group 2 treated praziquantel 60 patients.

- How to select and divide patients into 2 groups by open randomization method. Patients with odd number of records were treated with albendazole regimen for tapeworm larvae, while patients with even number of records were treated with praziquantel regimen for tapeworm larvae.

**** Research content***

- All patients were treated 3 times according to each regimen.
- Monitor patients during treatment at the Institute.
- Record all clinical signs during 3 course of treatment
- Test biochemical indicators GOT, GPT, creatinine, urea before and after each treatment session

- Magnetic resonance imaging after 6 months of treatment with the first dose (D180, when calculating the start date of treatment is D1). Evaluation and analysis of results with pre-treatment films.

*** Research drug**

- Praziquantel: Brand name: Distocid manufactured by Shin Poong, DAEWOO in the form of 600 mg tablets. HSD: 3/11/2020.

+ Dosage: 30mg/kg/24 hours divided into 2 times a day;

+ Treatment course: 15 days treatment; 30 days off;

+ Repeat the treatment dose and course as above for the 2nd and 3rd time.

- Albendazole: Brand name: Azental manufactured by Shin Poong DAEWOO in the form of 400 mg tablets; HSD: December 9, 2022.

+ Dosage: 20mg/kg/24 hours, used once a day;

+ Treatment course: 20 days; 30 days off;

+ Repeat the treatment dose and course as above for the 2nd and 3rd time.

- Note: Before entering the first course of albendazole treatment, treat adult pork tapeworms with Distocid 600mg at a dose of 15mg/kg/24 hours, single dose in fasting, monitor pulse, temperature, blood pressure and full status.

*** Monitoring during treatment**

- Patients participating in the study were monitored in the hospital.
- All medications are given to the nurse to drink in the ward, monitor for 30 minutes to see if the patient vomits, if vomiting within 30 minutes must take again.
- Daily visit by treating doctor and record clinical signs in treatment record.
- Handling unwanted effects (if any)
- The patient is discharged from the hospital, rests for 30 days at home, self-monitors and reports to the treating doctor by phone when experiencing abnormalities for advice and re-examination by appointment.

**** Rating indicators***

- Frequency and rate of clinical symptom reduction of tapeworm in the brain before and after each course and after 6 months of albendazol and praziquantel.
- The rate of eosinophils after treatment with each drug.
- Average values of GOT, GPT, Creatinine, Urea after each course of treatment of each drug.
- Percentage of patients with cyst reduction, no cyst, reduction in cyst size, cyst stage transition after 6 months of treatment with albendazole and praziquantel.
- Percentage of patients who have recovered, reduced symptoms and no symptoms after 6 months of treatment with albendazol and praziquantel.
- Index of drug safety:

+ Percentage of patients with symptoms and severity: fever, vomiting, allergies, diarrhea after taking albendazole and praziquantel.

+ The percentage of patients with GOT, GPT, creatinine, urea increased and the level increased after each course of treatment with each drug…

2.3. Data processing and analysis

- Collected data will be entered using Access 2010 software. Analyzed by Microsoft Excel, SPSS16.0 software
- Use statistical test when squared or Fisher's exact test when it is larger than the table 2x2 and has a value < 5 when comparing percentages; Use the t test when comparing two means.

2.4. Ethics in research

- This study complies with the regulations on ethical review in biomedical research of the Ministry of Health. The study was approved by the Institute's Scientific Council and Biomedical Ethics Committee.
- Patients are given specific information about their medical condition as well as the study process, duration of participation, benefits, possible risks, and then sign an agreement to participate in the study.
- Ensure the confidentiality of personal information about the patient's condition and the information in the research file.
- Evaluation of drug effectiveness is conducted under the supervision of professional staff.
- Respect the wishes of the participants when they want to stop participating in the study.

3. RESEARCH RESULTS

Table 3.1: Common clinical symptoms change after each course of treatment.

Symptom	Before treatment		After phase 1		After phase 2		After phase 3	
	Alb Quantit, rate (%)	Pra Quantity, rate (%)	Alb Quantity, rate (%)	Pra Quantity, rate (%)	Alb Quantity, rate (%)	Pra Quantity, rate (%)	Alb Quantity, rate (%)	Pra Quantity, rate (%)
Headache (60)	56 (93.3)	50 (83.3)	38 (63.3)	34 (56.7)	25 (41.7)	23 (38.3)	15 (25.0)	13 (21.7)
Convulsion (60)	41 (68.3)	31 (51.7)	16 (26.7)	19 (31.7)	5 (8.3)	4 (6.7)	0	0
Muscle tremors (60)	39 (65.0)	31 (51.7)	14 (23.3)	12 (20.0)	6 (10.0)	4 (6.7)	3 (5.0)	2 (3.3)
Numbness in limbs (60)	8 (13.3)	11 (18.3)	2 (3.3)	3 (5.0)	2 (3.3)	1 (1.7)	1 (1.7)	1 (1.7)

Note: Alb: albendazol, Pra: Praziquantel.

Symptoms gradually subsided after each course of treatment. The rate of headache after the third treatment was 25% in the albendazole group and 21.7% in the praziquantel group, but symptoms were significantly reduced compared to before treatment, mainly patients had occasional headaches. not as much headache as before treatment. Other symptoms such as myoclonus, numbness in the limbs are still present but the rate is low.

Table 3.2: Clinical results after 6 months of treatment.

Treatment / Protocol Effective	Albendazol Quantity, rate (%)	Praziquantel Quantity, rate (%)	Total Quantity, rate (%)
No symptoms	39 (65.0)	44 (73.3)	83 (69.2)
Relief symptom	21 (35.0)	16 (26.7)	37 (30.8)
Total	60 (100.0)	60 (100.0)	120 (100.0)
$\chi 2$	p > 0.05		

After 6 months of treatment, 83 patients had no clinical symptoms, accounting for 69.2%; 37 patients reduced symptoms, accounting for 30.8%, no patient had symptoms increased or remained the same. Of which, 65% of patients treated with albendazole and 73.3% of patients treated with praziquantel had no symptoms after six months of

treatment. There were 35% of patients treated with albendazole and 26.7% of patients treated with praziquantel reduced symptoms. The treatment effect of the 2 groups was similar (p > 0.05).

Table 3.3: Efficacy of treatment on the number of larval cysts of pork tapeworm in the cerebral hemisphere according to 2 regimens on MRI images.

Number of follicles	Albendazole		Praziquantel	
	Before treatment Quantity, rate (%)	After treatment Quantity, rate (%)	Before treatment Quantity, rate (%)	After treatment Quantity, rate (%)
No follicles		5 (10.9)		13(35.2)
01 follicle	2 (4.4)	3 (6.5)	5 (14.2)	1 (2.7)
2 - 5 follicle	10 (21.7)	17 (36.9)	14 (40.0)	15 (40.5)
> 5 follicle	30 (65.2)	20 (43.5)	15 (42.9)	8 (21.6)
Uncountable	4 (8.7)	1 (2.2)	1 (2.9)	0
Total	**46 (100.0)**	**46 (100.0)**	**37 (100.0)**	**37 (100.0)**
Fisher's exact test	p < 0.001		p < 0.001	
	p (After treatment alb and pra) > 0.05			

After treatment with cysts in the cerebral hemisphere, 10.9% of patients in the albendazole group and 35.2% in the praziquantel group were completely free of cysts. In the remaining patients, the number of follicles also decreased markedly. There was a significant difference before and after treatment in both regimens (p < 0.001).

Table 3.4: Efficacy of treatment on cyst size in cerebral hemisphere according to 2 regimens.

Follicle size	Albendazole		Praziquantel	
	Before treatment Quantity, rate (%)	**After treatment Quantity, rate (%)**	**Before treatment Quantity, rate (%)**	**After treatment Quantity, rate (%)**
< 5 mm	9 (19.6)	37 (90.2)	15 (40.5)	22 (91.7)
≥ 5 – 10 mm	31 (67.4)	4 (9.8)	20 (54.1)	2 (8.3)
>10 mm	6 (13.0)	0	2 (5.4)	0
Total	**46 (100.0)**	**41 (100.0)**	**37 (100.0)**	**24 (100.0)**
Fisher's exact test	p < 0.001		p < 0.001	
	p (After treatment alb and pra) > 0.05			

After treatment with cysts in the cerebral hemispheres, the size of the cysts was significantly reduced in both treatment regimens. After treatment, there are no cysts > 10mm in size; The cyst size of the group ≥ 5 - 10 mm decreased from 67.4% to 9.8% (reduced by 85.5%) in the albendazole regimen, similar to the praziquantel regimen, reduced by 84.6% (54.1). % before and 8.3% after treatment). The rate of cysts < 5 mm increased from 19.6% to 90.2% in the albendazole regimen (increased 78.2%); while in praziquantel regimen increased 55.8% (from 40.5% to 91.7%). There was a difference before and after treatment in both regimens (p < 0.001). Both albendazole and prizaquantel treatment groups had similar effects in reducing the size of cerebral hemisphere cysts after treatment (p > 0.05).

Table 3.5: Treatment effect on the number of larval cysts of pork tapeworm in the cerebral cortex/subcortical area according to 2 regimens.

	Albendazole		Praziquantel	
Number of follicles	**Before treatment Quantity, rate (%)**	**After treatment Quantity, rate (%)**	**Before treatment Quantity, rate (%)**	**After treatment Quantity, rate (%)**
No follicles		10 (37.1)		13 (38.2)
01 follicle	13 (48.2)	8 (29.6)	13 (35.3)	11 (32.4)
2 - 5 follicle	13 (48.2)	8 (29.6)	17 (50.0)	7 (20.6)
> 5 follicle	1 (3.6)	1(3.7)	4 (11.8)	3 (8.8)
Uncountable	0	0	1 (2.9)	0

Total	**27 (100.0)**	**27 (100.0)**	**34 (100.0)**	**34 (100.0)**
Fisher's exact test	p < 0.001		p < 0.001	
	p (After treatment alb and pra) > 0.05			

After treatment with subcortical cysts, 37.1% of patients in the albendazole group and 38.2% in the praziquantel group were completely free of cysts. In the remaining patients, the number of follicles also decreased markedly. There was a significant difference before and after treatment in both regimens (p<0.001). Statistical data showed that albendazole and prizaquantel treatment groups were equally effective in the number of cortical/subcortical tapeworm cysts (p>0.05).

Table 3.6: Therapeutic effect on the size of the cortical/subcortical pig tapeworm larval cyst size according to 2 regimens.

Follicle size	**Albendazole**		**Praziquantel**	
	Before treatment Quantity, rate (%)	**After treatment Quantity, rate (%)**	**Before treatment Quantity, rate (%)**	**After treatment Quantity, rate (%)**
< 5 mm	4 (14.8)	16 (94.1)	8 (23.5)	20 (95.2)
≥ 5 – 10 mm	20 (74.1)	1 (5.9)	17 (50.0)	1 (4.8)
>10 mm	3 (11.1)	0	9 (26.5)	0
Total	**27 (100.0)**	**17 (100.0)**	**34 (100.0)**	**21 (100.0)**
Fisher's exact test	p < 0.001		p < 0.001	
	p (After treatment alb and pra) > 0.05			

After treatment with cortical/subcortical cysts, the size of the cysts decreased significantly, the number of cysts less than 5 mm in the albendazole regimen increased from 14.8% to 94.1% (an increase of 84.3%) while Praziquantel regimen increased by 75.3% (from 23.5% to 95.2%). The number of cysts ≥ 5 – 10 mm in size decreased from 74.1% to 5.9% (92%) with albendazole regimen; and up to 90.4% (from 50% to 4.8%) with praziquantel regimen. There were no more patients with cysts >10mm in both regimens. Statistically significant difference between the reduction in the size of follicles before and after 6 months of treatment in both regimens p < 0.05. The difference was not statistically significant in the effectiveness of treatment to reduce the size of cortical/subcortical cysts with 2 regimens (p > 0.05).

Table 3.7: Change in the number of follicles after 6 months of albendazole treatment.

Before treatment	**After treatment**					**Total**
	Out of follicles	**1 follicle**	**2 – 5 follicles**	**>5 follicle**	**Uncountable**	
1 follicle	4	2				**6**
2 – 5 follicles	4	3	13	1		**21**
>5 follicle	0	2	12	17		**31**
Uncountable	0	0	0	1	1	**2**
Total	**8**	**7**	**25**	**19**	**1**	**60**

With the albendazole regimen, after 6 months of treatment, patients with 1 cyst of tapeworm in the brain had the rate of cyst completion accounted for 4/6 (66.6%), from 2-5 cysts, the rate of cyst completion accounted for 4/21 (19.1%), the more cysts, the lower the rate of emptying.

Table 3.8: Change in the number of follicles after 6 months of praziquantel treatment.

Before treatment	After treatment					Total
	Out of follicles	1 follicle	2 – 5 follicles	>5 follicle	Uncountable	
1 follicle	12	4				16
2 – 5 follicles	6	3	14			23
>5 follicle	3	0	5	11		19
Uncountable	2	0	0	0	0	2
Total	**23**	**7**	**19**	**11**	**0**	**60**

With praziquantel regimen, after treatment, patients with 1 cyst of tapeworm in the brain have the rate of cyst completion accounted for 12/16 (75%), from 2 to 5 cysts, the rate of cyst completion accounted for 6/23 (26). ,1%), the more cysts, the lower the percentage of cysts. For patients with > 5 follicles, the number of empty follicles accounted for only 3/19 (15.8%), the number of remaining cysts > 5 cysts accounted for 11/19 (57.9%)

Table 3.9: Follicular phase transition after 6 months of albendazole treatment (n=60).

Before treatment	After treatment 6 months				Total
	Out of follicles	Stage 3	Stage 4	Stage 5	
Stage 1,2,3	7	14	15	22	**58**
Stage 4	1	0	0	1	**2**
Total	**8**	**14**	**15**	**23**	**60**

With the albendazole regimen, after treatment, there were no patients with stage 1,2 cysts and 22 patients with active stage cysts (1,2,3) with calcifications (stage 5). But still 14 patients, accounting for 23.3%, still have active stage cysts (stage 3) despite the reduction in the number of cysts and the size of cysts.

Table 3.10: Follicular phase transition after 6 months of praziquantel (n=60).

Before treatment	After treatment 6 months				Total
	Out of follicles	Stage 3	Stage 4	Stage 5	
Stage 1,2,3	21	5	15	16	**57**
Stage 4	2	0	0	1	**3**
Total	**23**	**5**	**15**	**17**	**60**

With the praziquantel regimen, after treatment, there were no patients with stage 1,2 cysts and 16 patients with active stage cysts (1,2,3) with calcification. But there are still 5 patients accounting for 8.3% who still have active stage (stage 3) cysts, although the number of cysts and cyst size have decreased.

Since stage 5 cysts have calcified (cure), we included stage 5 cysts in the cure (no more cysts) and compared the treatment effects of the 2 regimens on the stages of cysts.

Table 3.11: Therapeutic effect of 2 regimens on the stages of larval cysts of pork tapeworm in the brain.

Index	Albendazole, Quantity, rate (%)	Praziquantel, Quantity, rate (%)	Total
Out of follicles	31 (43.7)	40 (56.3)	**71**
Stage 3	14 (73.7)	5 (26.3)	**19**
Stage 4	15 (50.0)	15 (50.0)	**30**
Total	**60**	**60**	**120**
Fisher's exact test	**p = 0.068**		

The therapeutic effect on brain stages of tapeworm cysts was the absence of active cysts, accounting for 43.7% with albendazole and 56.3% with praziquantel. The transition to stage 3 and 4 was similar (p > 0.05).

Table 3.12. Treatment effectiveness on MRI scans of 2 treatment regimens.

Index	Albendazol, Quantity, rate (%)	Praziquantel Quantity, rate (%)	Total
Out of follicles	31 (51.7)	40 (66.7)	71 (59.2)
Cyst reduction	29 (48.3)	19 (31.7)	48 (40.0)
Constant	0	1 (1.6)	1 (0.8)
Total	**60 (100.0)**	**60 (100.0)**	**120 (100.0)**
	Fisher's exact test, p > 0.05		

Results after treatment showed on MRI, 66.7% of patients treated with praziquantel and 51.7% of patients treated with albendazole had all the cysts on the brain. While the percentage of patients with cyst reduction after treatment was 48.3% and 31.7% respectively with the regimens using albendazole and praziquantel. There is no difference in the treatment effectiveness of the two regimens on MRI scans.

Table 3.13. Overall treatment effectiveness of the 2 study groups.

Index	Albendazole, Quantity, rate (%)	Praziquantel, Quantity, rate (%)	Total
Cured	23 (38.3)	32 (53.3)	55 (45.9)
Reduce disease	37 (61.7)	27 (45.0)	64 (53.3)
Not cured	0	1 (1.7)	1 (0.8)
Total	**60 (100.0)**	**60 (100.0)**	**120 (100.0)**
	Fisher's exact test, p > 0.05		

The rate of patients cured in the albendazole group was 38.3% and disease reduction was 61.7%. In the praziquantel group: the cure rate was 53.3% and the disease reduction was 45%, there was still 1 patient (1.7%) unchanged after 3 courses of treatment. This is a patient with tapeworm cysts in two locations: the cerebral hemisphere and the brain stem.

Table 3.14. Clinical adverse events during treatment.

Follow-up symptoms	After the first treatment		After the second treatment		After the third treatment	
	Alb	Pra	Alb	Pra	Alb	Pra
Tired	1	2	1	1	0	1
Fever	0	0	0	0	0	0
Abdominal pains	7	0	1	1	1	1
Nausea	2	5	0	1	0	1
Dizziness	0	2	0	1	0	1
Diarrhea	0	0	0	0	0	0
Rashes	0	1	0	1	0	1
Rash	0	0	0	0	0	0
Shortness of breath	0	0	0	0	0	0
Chest pain	0	0	0	0	0	0

During the course of 3 courses of treatment, most of the patients did not show any clinical increase. Only a few patients had symptoms such as fatigue when taking the medicine and mild abdominal pain, 7 (11.6%) cases in the first albendazole regimen, the following periods were reduced to 1 different case in each regimen. thing. There were 2 (3.3%) patients with nausea in the first treatment course with albendazole and 5 (8.3%) with praziquantel. In the following courses, there were only 2 different cases with nausea in 2 cases. treatment with praziquantel. There were 2 patients with symptoms of dizziness in praziquantel treatment regimen phase 1 and phases 2-3, each phase had 1 different patient with this symptom. All adverse events did not require intervention, the symptoms disappeared on their own within 24 hours.

Table 3.15: Some blood biochemical indices before and after treatment (n=120).

Index	Treatment session	Albendazole		Praziquantel		p
		Before treatment (a)	After treatment (b)	Before treatment (c)	After treatment (d)	
GOT (U/L)	Phase 1	38.1 ± 27.4	68.3±140.3	34.0±20.5	35.6±28.1	**p(a,b) < 0.05** p (c,d) > 0.05
	Phase 2	32.9 ± 12.9	48.1 ± 39.7	31.1±11.5	35.1±26.8	**p(a,b) < 0.05** p (c,d) > 0.05
	Phase 3	36.5 ± 13.9	50.2 ± 36.5	32.4±13.5	43.7±58.2	**p(a,b) < 0.05** p (c,d) > 0.05
GPT (U/L)	Phase 1	36.7 ± 19.2	85.9±110.1	32.3±23.1	41.9±41.7	**p(a,b) < 0.05** p (c,d) > 0.05
	Phase 2	34.3 ± 15.8	67.3 ± 43.0	30.6±14.2	37.5±23.6	**p(a,b) < 0.05** p (c,d) > 0.05
	Phase 3	41.2 ± 20.5	66.4 ± 49.4	33.6±17.0	45.9±101.0	**p(a,b) <0.05** p (c,d) > 0.05
Ure (mmol/L)	Phase 1	5.5 ± 1.1	5.4 ± 1.0	5.7 ± 1.8	5.3 ± 1.3	p(a,b) > 0.05 p (c,d) > 0.05
	Phase 2	5.1 ± 0.7	5.3 ± 0.8	5.3 ± 1.3	4.9 ± 1.2	p(a,b) >0.05 p (c,d)>0.05
	Phase 3	5.0 ± 0.6	5.9 ± 4.8	6.0 ± 5.5	6.4 ± 6.8	p(a,b) >0.05 p (c,d)>0.05
Creatinin (µmol/	Phase 1	79.8 ± 14.4	80.5 ± 11.0	82.4±13.6	82.2 ± 13.1	p(a,b) >0.05 p (c,d)>0.05
	Phase 2	80.6 ± 8.2	80.2 ± 8.9	77.5±12.9	78.9 ± 11.9	p(a,b) >0.05 p (c,d)>0.05
	Phase 3	79.4 ± 7.6	80.5 ± 7.5	78.9±11.0	78.1 ± 10.9	p(a,b) >0.05 p (c,d)>0.05

After each treatment period, liver enzymes GOT and GPT both increased compared to before treatment. However, only the albendazole treatment group increased more and had a statistically significant difference compared to before treatment with $p < 0.05$. In all cases, after a period of stopping the drug, GOT and GPT enzymes returned to normal, no treatment intervention was required.

4. DISCUSSION

4.1 Development of the treatment process

Total of 120 patients infected with brain tapeworm larvae participating in the study were divided into 2 groups using albendazole and praziquantel treatment regimens. Distribution of patients with tapeworm larvae in the brain into 2 treatment groups occurs in all age groups, however the majority of patients are concentrated in the age groups 41 - 50, 51-60 and 61-70. The average age of patients with tapeworm larvae in the brain in the albendazole treatment group, 50.17 ± 10.03, is the same as the praziquantel treatment group, 52.28 ± 12.97 years old, with $P > 0.05$. The majority of patients with tapeworm larvae in the brain treated in the two groups are of Kinh ethnicity, accounting for 50% and 63.3%, Tay and Thai, accounting for 6.7% to 21.7%. In addition, we also met a number of patients with brain tapeworm larvae from other ethnic groups such as Dao, Day, H'mong, Ha Nhi, Khang Nung, Xinh Mun. Through Fisher's exact test analysis, it showed that between the 2 treatment groups, the ethnic groups allocated to the randomized study were very similar ($p > 0.05$). The random selection of patients into the 2 treatment groups showed that the patients' occupations were quite evenly distributed in the 2 groups ($p > 0.05$). However, the majority of patients were farmers with 63.3% and 56.7% in the groups using albendazole and praziquantel, respectively.

The proportion of patients in the praziquantel regimen who had passed out tapeworm larvae was as high as 8.3%, while patients in the albendazole group had a rate of passing out tapeworm segments of 1.7%.

The difference in the rate of symptoms in the two study groups was not statistically significant. Patients (patients) hospitalized in both groups mainly had neurological symptoms such as headaches up to 93.3% and 83.3%, convulsions 68.3% and myoclonus 51.7% 61, 7 and 55%. There are also other symptoms such as fainting, memory loss, numbness in the limbs... 10% of patients have balance disorders, muscle weakness, 2.5% of patients have tapeworm cysts under the skin. . The distribution of disease detection time of patients in the 2 groups did not differ. Some patients are detected quite early, but there are also many patients who do not seek medical examination until after 2-5 years or after 5 years. The number of late medical examinations accounts for a higher proportion in both groups. In the two groups of patients, the common clinical symptoms were quite similar. The first and most common in the two groups were convulsions, up to 66.7% and 46.7% in the albendazole and praziquantel groups, respectively; Next is headache and numbness. Some patients did not even show clinical symptoms, accounting for 6.7% of the praziquantel group.

When hospitalized, patients in both groups had increased clinical symptoms compared to the baseline with rates up to 66.7% and 75.0% in the albendazole and praziquantel treatment groups, respectively. However, up to 18.3% and 21.7% of patients in the albendazole and praziquantel groups, respectively, had reduced symptoms compared to baseline. But the indices of both groups did not have a statistically significant difference. And only 11.6% and 6.75 patients in the above two groups, respectively, had no change in clinical symptoms until hospitalization for treatment.

4.2. Effective treatment of pork tapeworm larvae in the brain of 2 treatment regimens

Through clinical monitoring and based on the results of brain MRI before and after treatment, we obtained the following results: After 6 months of treatment (including 3 treatment cycles), 83 patients had no symptoms. 69, 2%; 37 patients reduced symptoms, accounting for 30.8%. 73.3% of patients treated with praziquantel had no symptoms after six months of treatment, while this rate in the albendazole regimen was 65%. 35% of patients treated with albendazole and 26.7% of patients treated with praziquantel had symptom relief after 6 months of treatment. However, there was no statistically significant difference between clinical treatment results when using these two drugs to treat patients with cerebral tapeworm larvae in the study.

After 6 months of treatment (including 3 treatment cycles), the remaining symptoms are still headaches (2.5%), occasional headaches (20.8%), and occasional myoclonus (4.2%). Symptoms of hand numbness, memory loss, double vision are only seen in 1-2 patients. There was no difference in the clinical outcomes of the 2 treatment regimens ($p > 0.05$).

After treatment with the subcortical cyst group, 37.1% of patients in the albendazole treatment group and 38.2% of the praziquantel group had complete cyst resolution. In the remaining patient, the number of follicles also decreased markedly. There was a significant difference before and after treatment in both regimens ($p < 0.001$). Statistics show that albendazole and prizaquantel treatment groups are equally effective against subcortical tapeworm cysts ($p > 0.05$).

After treatment with the cortical/subcortical cyst group, the size of the cysts decreased significantly, the number of cysts smaller than 5 mm in the albendazole cyst regimen increased from 14.8% to 94.1% (an increase of 84.3 %) while Praziquantel regimen increased by 75.3% (from 23.5% to 95.2%). The number of follicles ≥ 5 - 10 mm in size

decreased from 74.1% to 5.9% (92%) with albendazol regimen; and up to 90.4% (from 50% to 4.8%) with praziquantel regimen. There were no more patients with cysts > 10mm in both regimens. There is a statistically significant difference between the reduction in cyst size before and 6 months after treatment in both regimens, $p < 0.05$. However, there is no statistically significant difference in the cyst size reduction index before and after 6 months of treatment when comparing the treatment results of these two regimens $p > 0.05$.

Treatment results with the cerebral hemisphere cyst group showed that 35.2% of patients in the praziquantel treatment group and 10.9% of the albendazole treatment group had complete cyst resolution. In the remaining patient, the number of follicles also decreased markedly. There was a significant difference before and after treatment in both regimens ($p < 0.001$). Statistics show that albendazole and prizaquantel treatment groups are equally effective against tapeworm cysts in the cerebral hemisphere ($p > 0.05$). In this group, the size of the cysts was significantly reduced in both treatment regimens. After treatment, there are no cysts > 10mm in size; Cyst size of the ≥ 5 - 10 mm group decreased from 67.4% to 9.8% (85.5% reduction) in the albendazole treatment regimen, similar to the praziquantel regimen, which decreased to 84.6% (54.5%), 1% before and 8.3% after treatment). The rate of cysts < 5 mm increased from 19.6% to 90.2% in the albendazole regimen (78.2% increase); while in the regimen using praziquantel increased 55.8%.

Among the total number of patients with cysts in stages 1 and 2, the rate of patients with cysts free after albendazole treatment was 54.8%, the rate of cyst reduction was 71.0%, while this rate was in the group treated with albendazole. praziquantel were 45.2% and 29.0%. albendazole had better results than praziquantel, but the difference was not statistically significant ($p > 0.05$). For patients with tapeworm cysts at stages 3 and 4, the rates of cyst resolution and cyst reduction when treated with praziquantel were 65.0% and 58.8%, respectively, and these rates were in the treatment group with albendazole were 35.0% and 41.2%. The treatment regimen with praziquantel had better results than albendazole, but the difference was not statistically significant ($p > 0.05$).

According to post-treatment results shown on MRI scans, 66.7% of patients treated with praziquantel and 51.7% of patients treated with albendazole had no tapeworm cysts on the brain. While the percentage of patients with cyst reduction after treatment was 48.3% and 31.7% respectively with the regimens using albendazole and praziquantel. There is no difference in the treatment effectiveness of the two regimens on MRI scans.

In this study, based on the remission of clinical symptoms and changes in cysts of Tapeworms on cranial MRI. We found that both albendazole and praziquantel are effective in the treatment of tapeworm larvae. Patients were clinically monitored through treatment sessions and brain MRI scans were performed 2 months after the third treatment session. After treatment, the number of tapeworm larvae is still many, but the cysts decrease in size and stage of damage. Multiple stage 4 cysts and calcified cysts. These are tapeworm cysts before treatment in an active form, after treatment under the action of specific drugs, the cysts die off creating sequelae in the brain, these sequelae can still be Causes symptoms such as headaches and epilepsy....

Author Sotelo has applied the treatment regimen praziquantel 50mg/kg x 15 days. After 3 months of treatment, 50% of patients had no clinical symptoms, 62% of pork tapeworm cysts disappeared and 72% of cyst sizes decreased.

According to the results of Vianna's study, 27 patients with brain tapeworms were treated with praziquantel in gradually increasing doses up to 50 mg/kg/day in combination with dexamethasone for 21 days. The patients were

followed during and after treatment and those followed for one year had their immunoassays (indirect immunofluorescence and ELISA) repeated at this time. Headache was the most common symptom during treatment, occurring in 37% of patients. One year after treatment 72.2% of patients finished treatment with improvement. Immunoassays became negative in 45.4% of patients in serum and 42.8% in cerebrospinal fluid. There was no correlation between clinical progression and immunoassays.

Often, the first few days after the administration of antiparasitic agents to patients with neurocysticercosis there is a recrudescence of neurological symptoms, most importantly decompensation of intracranial pressure and the onset of seizures or worsening of pre-existing ones, owing to peri-lesional inflammation due to degeneration of the parasite; this condition can be life-threatening. The severity of inflammation is proportional to the parasitic burden, resulting in more severe manifestations in individuals with greater cyst loads.[9] A common approach to ameliorating this problem is the concomitant administration of corticosteroids to reduce edema, the inflammatory response, and intracranial hypertension. [6] Special attention should be paid to patients with high cyst loads, to whom the administered antiparasitic treatment causes an abrupt degeneration of cysts that may lead to severe inflammation and seizures. [11] In such cases corticosteroids should be administered before the antiparasitic agents. The single death reported in the study by Takayanagui et al (the only death among patients of all trials included in this meta-analysis) was the result of increased intracranial pressure, which, however, pre-existed at the beginning of the trial.[12] In 5 out of 6 studies included in our meta-analysis, corticosteroids were administered to patients.[2,4,10,12] Only in the study by Medina et al were corticosteroids not administered; adverse events were not reported in this study.[8]

It is believed by several experts that many cysts degenerate spontaneously over time, which may lead to the conclusion that the results of the evaluable studies may be biased. [33] Since it is not clear up to what extent this opinion is true, we analyzed studies that included patients with cystic lesions without perilesional enhancements or other evidence of surrounding inflammation, as evidence of a possible degenerative process, to rule out such a possibility. Antihelminthic drugs are effective against viable cysts, but not on remnants, granulomas, and calcifications of dead cysts. Thus, both outcomes we chose to study the total disappearance of cysts and reduction of cyst are useful indicators of the effectiveness of the administered therapy, because they estimate the effectiveness of the administered agents for lesions on which the agents are active.

There are some limitations in our meta-analysis that should be considered. First, one may claim that the number of the studies and the number of patients are too small to allow a definitive conclusion regarding the results of the compared therapies. This small sample size is important because it leads to large confidence intervals. In addition, publication bias cannot be appropriately assessed in a small set of studies. Also, among the studies selected there are only 2 RCTs in a total of 6 comparative trials, which prevents us from applying the usually applied methodology in obtaining an overall quality assessment of the included studies.[2,10]

The outcomes in our meta-analysis suggest that albendazole is more effective than praziquantel in controlling seizures in the affected patients and in leading to the total disappearance of cysts and, subsequently, the cure of patients with neurocysticercosis. However, in the sensitivity analysis of the total disappearance of cysts, excluding the study by Sotelo et al,[19] no significant difference was found between the drugs, although the odds ratio was rather similar to the analysis that included the study by Sotelo et al.[10] This loss of statistical significance can be explained by the loss of power in the sensitivity analysis due to exclusion of the aforementioned study. Regarding other outcomes, there have

been no statistically significant differences between albendazole and praziquantel in reduction of total number of cysts, mortality, total adverse events, and development of intracranial hypertension due to the administered therapeutic agents. Control of seizures and total disappearance of cysts were chosen as outcomes in our meta-analysis, because they are easily defined and quantitatively measured. In addition, new-onset seizures are among the most common symptoms that lead patients to seek medical care, and their resolution is one of the major goals of therapy.

According to a summary of research by author Dimitrios and colleagues in 2008, comparing the results of 6 studies treating patients infected with tapeworm larvae in the brain with treatments with albendazole and praziquantel as follows:

- Study 1 (4 study groups) used albendazole 15mg/kg/day for 1 month for group 1; 15mg/kg/day for 8 days for group 2; praziquantel 50mg/kg/day for 15 days for group 3 and praziquantel 50mg/kg/day for 8 days for group 4. All groups were randomized and the patients were infected with tapeworm cysts in the brain parenchyma. The results showed that the reduction rate of tapeworm larvae of albendazole was 84.9% of praziquantel was 55.1%; The rate of tapeworm cysts disappearing after albendazole treatment is 65.3% while that of praziquantel is 38.5%.
- Study 2 used 2 regimens of albendazole 15mg/kg/day for 30 days and praziquantel 50mg/kg/day for 15 days. The results of this study showed that the cystic disappearance rates of albendazole and praziquantel were 80% and 79.2% similar.
- Study 3 used albendazole 20mg/kg/day for 21 days in the first regimen and the second regimen used praziquantel 50mg/kg/day for 21 days. The results showed that convulsions were controlled by 91.7% by albendazole, 41.7%. The rate of reducing tapeworm cysts of albendazole and praziquantel was 88.1% and 50%, respectively; while the rate of tapeworm cysts disappearing with albendazole is 55% and with praziquantel is 15%.
- Study 4 used albendazole 15mg/kg/day for 8 days in the first regimen and regimen 2 used praziquantel 50mg/kg/day for 8 days. The ratio of muscle seizure control with praziquantel was 605, while the This rate of albendazole is 90.9%. The rate of tapeworm cyst reduction of the two regimens is almost the same, 89.8% for albendazole and 79.2% for praziquantel; However, the rate of cyst disappearance of the two regimens is different, while that of praziquantel is 20%, and that of albendazole is up to 72.7%.
- Study 5 used albendazole 15mg/kg/day for 8 days in the first regimen and the second regimen used praziquantel 50mg/kg/day for 15 days. The results of this study showed that myoclonic seizure control rates of the two regimens were similar at 63.5% for albendazole and 57.8% for praziquantel. The rate of larval cysts and the disappearance of tapeworm cysts of the two regimens were also quite similar with albendazole and praziquantel, respectively 41.2% - 41.5% and 28.1% - 31.5%.
- Study 6 used albendazole 15mg/kg/day in 2 divided doses for a week in the first regimen and in the second regimen using praziquantel 100mg/kg in 3 divided doses 2 hours apart in 1 day. Studies have shown that the symptom control rate of myoclonic seizures is up to 100% with albendazole while that of praziquantel is 77.8%; The cyst reduction rates of albendazole and praziquantel were 89.1 and 59.3%, respectively; while the percentage of cysts disappearing is 50% and 30%, respectively.

Neurocysticercosis is an endemic disease in many developing countries, and it may expand to the developed world, mainly as a result of immigration. Estimations report around 50 million new cases worldwide.[15] To our knowledge, until now the guidelines for the treatment of cysticercosis are the result of a consensus by a panel of experts in the subject. [5] Specifically, for viable parenchymal cysts the recommendations are based on evidence obtained from

multiple case series with or without intervention, including dramatic results in uncontrolled experiments (level II-3 recommendation, which is considered a weak category of evidence), and on opinions of respected authorities, based on clinical experience, descriptive studies, and case reports or reports of expert committees (level III recommendation). Although these recommendations support the use of antiparasitic treatment, they do not point to either albendazole nor praziquantel as the drug of choice for this type of neurocysticercosis.

Often, the first few days after of praziquantel could be explained by the interaction between praziquantel and corticosteroids, which results in decreased serum concentration of praziquantel.[14] Also, praziquantel interacts with anti-epileptic drugs thus altering its bioavailability. In contrast, corticosteroids interact with albendazole by decreasing the rate of elimination of albendazole sulfoxide, which is the active metabolite of albendazole, thus increasing serum concentrations of albendazole sulfoxide.[1,3,7,13]

4.3. Some unwanted effects after taking the drug

The results showed that some undesirable effects after taking the drug of both groups were rare, symptoms were usually mild at the end of the first treatment. Treatment with albendazole regimen, there were 7 cases (11.6%) pain in the epigastrium, 2 cases (3.3%) feeling of nausea, but when used with drugs to support the stomach, the patient had no symptoms, 1 case There were signs of fatigue during the first treatment period. While the 2nd and 3rd treatment with albendazole regimen, there was only 1 case of epigastric pain in each episode and 1 case of fatigue in the 2nd session. Meanwhile, in the praziquantel regimen there were 5 cases (8.3%) patients felt nausea, no vomiting, 2 cases (3.3%) felt dizzy when taking the drug, 2 cases showed signs of fatigue, 1 case (1.7%) was different in each patient. During treatment with praziquantel, rashes appear after each treatment session but usually disappear after 24 hours.

Like some other good studies, in our study, the average GOT index before and after the first round of treatment did not have a statistically significant difference, however, this index in the second round of treatment was not statistically significant. 2 and 3 increased after treatment and there was a statistically significant difference. The average GPT index after treatment sessions 1, 2, and 3 all increased compared to before treatment and had a statistically significant difference. With blood urea index, there was only a statistically significant difference in round 1. Creatinine index had no difference after treatment rounds. After each course of treatment, liver enzymes GOT and GPT both increased compared to these indexes before the treatment sessions. The GOT index in the albendazole treatment group increased and showed a statistically significant difference in each treatment period with $p < 0.05$. In the praziquantel group, liver enzymes increased, but not different from before treatment ($p > 0.05$). However, after a period of discontinuation of the drug, the GOT and GPT enzymes returned to normal, without treatment intervention. Urea, creatinine before and after treatment had no difference in both groups.

With the praziquantel treatment regimen, the results showed that almost no change in liver and kidney function before and after treatment, and in some cases a slight increase in liver enzymes (<100U/L). With albendazole treatment regimen: GOT and GPT enzymes mostly increased slightly (<3 times normal value), moderately increased (>4 times) but did not exceed 10 times normal value. And GOT and GPT enzymes usually return to normal 1 month after stopping the drug.

5. CONCLUSION

Effective treatment of swine tapeworm larvae in the brain with albendazole and praziquantel:

- Clinical treatment effectiveness: After 6 months of treatment, the main clinical symptoms such as headaches, convulsions, myoclonus... were significantly improved, only 25% remained in the albendazole and 21. 7% of the praziquantel group still had headaches; However, the level of headache decreased markedly. There were no more patients with seizures, the number of myoclonus accounted for 5.0% in the albendazole group and 3.3% in the praziquantel group.

Clinical effectiveness after treatment: the rate of patients with no clinical symptoms of albendazole is 65% and praziquantel is 73.3%. The proportion of patients with reduced clinical symptoms in the albendazole regimen is 35% and that of praziquantel is 26.7%, the treatment effect of albendazole at a dose of 20mg/kg/24 hours x 20 days x 3 times and praziquantel at a dose of 30mg/kg/24 hours hours x 15 days x 3 episodes, each episode 1 month apart in similar patients infected with pork tapeworm larvae in the brain.

Treatment effectiveness on hydatid cysts determined by MRI:

+ Patients with a small number of cysts in the brain (1 cyst) had a high rate of cyst clearance 66.6% with albendazole and 75% with praziquantel, patients with many cysts were less effective.

+ All cysts in stages 1 and 2 responded well to treatment drugs. After treatment, there were no cysts left in stages 1 and 2 or cysts that had progressed to stages 3, 4, 5 with both albendazole and praziquantel .

+ The percentage of patients who lost their cysts after treatment with albendazole was 51.7%, and praziquantel was 66.7%. The rate of patients with cyst reduction after treatment with albendazole was 48.3% and praziquantel was 31.7%.

- General therapeutic effect:

After 6 months of treatment, clinical and MRI cure results with albendazole regimen were 38.3%, disease reduction was 61.7%. With praziquantel regimen: cure rate is 53.3%, disease reduction is 45%. The general treatment effects of albendazole and praziquantel are the same.

- Drug safety:

+ Symptoms of undesirable effects after treatment are mild and the patient spontaneously resolves after stopping the drug or undergoing symptomatic treatment.

+ GOT and GPT tests before and after treatment with praziquantel did not detect any changes. Meanwhile, patients treated with Albendazole had mild and moderate increases in liver enzymes. Liver enzymes returned to normal after 1 month off the drug. Urea and creatinine did not change before and after albendazole and praziquantel treatments.

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