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THE EFFICACY AND SAFETY OF THREE 30-DAY COURSES OF ALBENDAZOLE IN PATIENTS WITH NEUROCYSTICERCOSIS

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ЭФФЕКТИВНОСТЬ И БЕЗОПАСНОСТЬ ТРЕХ 30-ДНЕВНЫХ КУРСОВ АЛЬБЕНДАЗОЛА У БОЛЬНЫХ НЕЙРОЦИСТИЦЕРКОЗОМ

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Авторы внесли одинаковый вклад в эту работу и выступают в качестве первых авторов.

Abstract: Albendazole is one of the drugs indicated for the treatment of neurocysticercosis. However, data on the treatment outcome of a long course of this drug is scarce. This study aims to investigate the efficacy and safety of three 30-day courses of albendazole in patients with neurocysticercosis. **Methods:** The diagnosis of neurocysticercosis was based on epidemiological, clinical and laboratory criteria as guided by the Vietnamese Ministry of Health. Sixty patients with a mean age of 50.17 ±10.03 years old, with 86.7% (95% CI: 77.8 – 95.5%) men, were involved in this study. Patients received three 30-day courses of albendazole with an intermittence of 20 days. Additional treatment included steroids, anticonvulsants or analgesics. Based on brain magnetic resonance imaging 6 months after the therapy, the efficacy was classified as cure (viable cysts not discernible), improvement (50% or more cysts disappeared or calcified) or inefficacy (changes in less than 50% of the cysts). The safety was determined based on the changes of biochemical parameters after each treatment course. **Results:** The most common clinical presentations were headache (90.0%, 95% CI: 82.2 – 97.8) and/or seizure (68.3%, 95% CI: 56.2 – 70.4), followed by other symptoms such as fainting, memory loss, and limb numbness. Active cysts were discovered in all cases and located mainly in the parenchymal region. After therapy, the rates of cure, improvement or inefficacy were 43.3% (95% CI: 30.4 – 56.2%), 51.7% (95% CI: 38.7 – 64.7%) and 5.0% (95% CI: 0 – 10.7%), respectively. Liver enzymes were slightly higher compared to those before therapy and mostly returned to normal ranges after drug interruption. Alanine aminotransferase levels before the 3rd course were higher than values before the first and second courses. No abnormalities in blood urea or creatinine after therapy were reported. **Conclusions:** Three 30-day cycles of albendazole appear to have good efficacy and tolerability in patients with neurocysticercosis.

Keywords: neurocysticercosis, efficacy, safety, albendazole, long course, Vietnam.

Резюме: Альбендазол является одним из препаратов, показанных для лечения нейроцистицеркоза, однако данные об исходе лечения длительным курсом этого препарата немногочисленны. Настоящее исследование направлено на изучение эффективности и безопасности трех 30-дневных курсов альбендазола у пациентов с нейроцистицеркозом.

Методы. Диагноз нейроцистицеркоза был основан на эпидемиологических, клинических и лабораторных критериях в соответствии с рекомендациями Министерства здравоохранения Вьетнама. В исследование вошли шестьдесят пациентов мужского пола со средним возрастом 50,17 ± 10,03 года и 86,7% (95% ДИ: 77,8–95,5%). Пациенты получали три 30-дневных курса альбендазола с перерывом в 20 дней. Дополнительное лечение включало стероиды, противосудорожные препараты или анальгетики. На основании магнитно-резонансной томографии головного мозга через 6 месяцев после терапии эффективность классифицировали как излечение (жизнеспособные кисты не были различимы), улучшение (исчезновение или кальцификация 50% и более кист) или неэффективность (изменения были зарегистрированы менее чем в 50% кисты). Безопасность определяли по изменению биохимических показателей после каждого курса лечения.

Результаты. Наиболее частыми клиническими проявлениями были головная боль (90,0%, 95% ДИ: 82,2–97,8), судороги (68,3%, 95% ДИ: 56,2–70,4), за которыми следовали другие симптомы, такие как обмороки, потеря памяти, онемение конечностей. Активные кисты были обнаружены во всех случаях и располагались преимущественно в паренхиматозной области. После терапии частота излечения, улучшения и неэффективности составила 43,3% (95% ДИ: 30,4–56,2%), 51,7% (95% ДИ: 38,7–64,7%) и 5,0% (95% ДИ: 0–10,7%) соответственно. Показатели печеночных ферментов в сыворотке крови печени были несколько выше по сравнению с таковыми до терапии и в большинстве случаев возвращались к нормальным значениям после прекращения приема препарата. Уровень аланинаминотрансферазы перед 3-м

курсом был выше, чем до первого и второго курсов. Отклонений в показателях мочевины и креатинина в крови после терапии не зарегистрировано. Выводы: Три 30-дневных цикла альбендазола обладают хорошей эффективностью и переносимостью у пациентов с нейроцистицеркозом.

Ключевые слова: нейроцистицеркоз, эффективность, безопасность, альбендазол, длительный курс, Вьетнам.

Introduction

Cysticercosis is a disease caused by the larval stages (cysticercus) of the pork tapeworm (*Taenia solium*). The disease is endemic in most low- and middle-income countries and also reported in industrial countries [24]. The clinical manifestations of the disease depend on the number, location, as well as response of the body human to these cysticerci [9]. Neurocysticercosis (NCC) is the most common form of the disease and responsible for significant morbidity. Neurocysticercosis is the cause of 30% of all epilepsy cases worldwide in addition to other neurological symptoms including chronic headaches, focal neurologic deficits, intracranial hypertension, and cognitive decline [25].

Treatment of NCC is mostly symptomatic. Nevertheless, antiparasitic drugs for the destruction of cysts are important [6]. Between the two anthelmintics mostly commonly used, albendazole may be superior to praziquantel because of its better penetration into the central nervous system, lower cost, and lesser interaction with other drugs [20]. Several studies have investigated the efficacy of albendazole, and a dose of 15 mg/kg/day has generally been accepted [2, 3, 10-12]. However, there is still considerable disagreement concerning the length of therapy. Most studies have relied on a one to four-week course, with observed cyst disappearance in 25% to 37% of case [2, 3, 10-12]. Due to the low efficacy of this regime, a longer duration (more than one 4-week course) might be an appropriate approach, but there is little information on the treatment outcome of this prolonged regime [17]. This study aims to investigate the efficacy and safety of three 30-day courses of albendazole in patients with NCC.

Materials and methods

Ethical consideration

This research is part of thesis work for the fulfilment of Doctor of Philosophy in Health Studies. It obtained clearance from the ethics committee of the Vietnam National Institute of Malariology, Parasitology and Entomology

(NIMPE). Written or verbal consent was obtained from all the patients or their legal representatives.

Study design

This prospective study was carried out at the Specialized Parasitic Clinic, NIMPE during January 2017 and December 2020. All patients visiting the clinic with clinical symptoms/signs suspected of NCC were screened for the infection. Criteria for inclusion were subjects more than five years old and diagnosed with NCC, with willingness to complete antiparasitic therapy and follow-up examination after treatment. Criteria for exclusion were pregnant women, subjects exhibiting acute diseases or concurrent parasitic diseases, or having a known history of allergy to benzimidazole.

After informed consent was obtained, a detailed history of symptoms, duration and progression of the disease, in addition to sociodemographic data, was recorded. A careful systemic and neurologic examination was done, followed by laboratory investigations. Blood examination included blood cell counts and standard tests of biochemistry. Serum enzyme-linked immunosorbent assay (ELISA) for certain infections common in Vietnam (cysticercosis, fascioliasis, strongyloidiasis, gnathostomiasis, toxocariasis, amebiasis) was performed using reagents from Cortez Diagnostics Inc. (USA) following manufacturer instructions. Brain magnetic resonance imaging (MRI) was used to determine the number and stages of cysts. Stool samples were collected and examined for intestinal helminths or protozoans.

The treatment: Patients with vesicular, colloidal, or granular cysts on MRI received three 30-day courses of albendazole at a daily dose of 15 mg/kg of body weight. The intermittence between the courses was 20 days. Before taking albendazole, patients received praziquantel 20 mg/kg to treat adult worms [22]. Additional treatment included steroids to decrease inflammation and anticonvulsant or analgesic drugs as needed.

Follow-up: Clinical assessment was performed at the start of and during therapy. Blood samples were taken at the beginning and the end of all three courses. Brain MRI was performed 6 months after completion of therapy to assess treatment outcome.

Definition: As guided by the Vietnamese Ministry of Health, diagnosis of cysticercosis was based on epidemiological, clinical, and laboratory criteria based on well-known ones [4, 5]. Epidemiologic criteria include ingestion of raw vegetables or living in endemic areas. Suggestive manifestations of NCC are late-onset seizures, focal neurologic deficits, intracranial hypertension, chronic headaches, or cognitive decline. Laboratory criteria are: (1) positive biopsy results of cysts; (2) pathognomonic lesions on computed tomography (CT) or MRI (cysts with "hole-with-dot" appearance); (3) parasites discovered by funduscopic examination; and (4) a positive result by serum ELISA [22]. On MRI, location of cysts was grouped into cortex/subcortex, hemisphere, subarachnoid, or intraventricular. Based on stage, they were classified as viable (vesicular, colloidal, granular) or dead (calcified) cysts [8, 26]. Treatment outcome was classified based on the resolution of cystic lesions as follows: complete resolution/cure wherein viable cysts were not discernible on MRI; partial resolution/improvement wherein 50% or more cysts disappeared or calcified; or no resolution/inefficacy wherein changes were reported in less than 50% of the cysts. Reference ranges were: 1–35 U/L for aspartate aminotransferase (AST) and alanine aminotransferase (ALT); 1.8 – 7.1 mmol/L for urea; and 44–97 μmol/L (female) and 53–106 μmol/L (male) for creatinine [23]. Mild elevation was designated as liver enzyme levels less than five times the upper limit of the normal value. Greater than 15 times the upper limit was designated as severe elevation.

Statistical analysis

Data analysis was performed with SPSS 16.0 (SPSS-IBM Company). Categorical variables were expressed as case number (n) and percentages, while

numerical variables were expressed as mean and standard deviation ($\overline{X} \pm$ SD). A paired sample t-test was used to determine the mean difference of continuous variables at different time points. P-values less than 0.05 were considered statistically significant.

Results

Table 1. Baseline patient characteristics (n=60).

* same patients with cysts at different sites.

Sixty patients aged between 28 – 68 years participated in the study. The male to female ratio was 6.5/1. All patients met the epidemiologic criteria due to a history of eating raw vegetables in addition to living in north and central Vietnam where active transmission of taeniasis and cysticercosis has been reported. The most common clinical presentations were headache and/or seizure, followed by other symptoms such as fainting, memory loss, or limb numbness. Only one patient had a history of defecating proglottides or subcutaneous cysts. On brain MRI, cysts were located in different locations, but mainly in the parenchymal region (cerebral hemisphere (83.3%), cortical/subcortical region (41.7%), or cerebellum (10.0%). Multiple cysts (≥ 2) were discovered in 48/50 (96%) cases in the hemisphere, 14/25 (56%) cases in cortical/subcortical regions, and 3/6 (50%) cases in the cerebellum. In the intraventricular or subarachnoid region, only a single cyst was discovered. Vesicular cysts occurred in 60 (100%) cases, and calcified cysts in one case (cerebellum). Elevation of AST occurred in 19 (31.7%) patients and of ALT in 24 (40.0%) patients. Average liver enzyme levels were slightly higher than normal reference, whereas the levels of urea and creatinine were within the normal ranges (Table 1).

Table 2. Efficacy of antiparasitic treatment (n=60).

After antiparasitic therapy, almost all (95.0%) patients had radiological improvement, but a complete resolution was reported in less than half of the participants (43.3%). There were two patients with no cystic resolution, and one patient showed an increase in the number of cysts six months after treatment (Table 2). Clinical examination showed that 23/41 (56.1%) patients with seizures were completely cured, and 25/54 (46.3%) patients having headaches recovered. Of the patients with loss of memory or fainting, the rates of complete recovery were (6/14) 42.9% and (11/17) 64.7%, respectively.

Table 3. Biochemical parameters before and after therapy (n=60).

* Mean ALT concentration before the third course was higher than that before the first and second courses ($p<0.001$).

Table 3 shows changes in biochemical parameters after treatment. The levels of liver enzymes after treatment were all above the normal ranges and significantly higher compared to those before the antiparasitic course. The percentages of patients with increased AST after the 1st, 2nd and 3rd course were 66.7%, 75% and 85% respectively. There were 50 (83.3%), 55 (91.7%), and 49 (81.7%) cases having elevated ALT levels after the first, second, and third course. Most of them had mild or moderate elevation; only one patient had a severe elevation of liver enzymes. After drug interruption, liver enzyme levels mostly returned to normal ranges equivalent to pretreatments levels. However, ALT levels before the 3rd course were higher than the baseline as well as the normal range. Urea and creatinine concentrations were within normal limits at all examinations. The only exception was that urea concentration after the 2nd and 3rd course increased

slightly compared to levels before the course but was within normal ranges. During therapy, some patients developed headaches, vomiting, or exacerbation of seizures.

Discussion

This study was carried out to investigate the efficacy and safety of a prolonged regime of albendazole in patients with NCC. Our results suggest that three 30-day cycles of albendazole have good efficacy against NCC. Most of the patients (95%) had radiological improvement, and a complete clearance of cysts on MRI was reported in 43.3% of cases. Clinical examination showed that about half of the patients had improvement, but these results were not included in the efficacy evaluation. Clinical evaluation has been considered inappropriate because some symptoms, such as seizures, can present long after cyst clearance [8,9]. The complete resolution rate in our patients (43.3%) was slightly higher than that in previous observations (reporting cure rates ranging from 25% to 37%) [2, 3, 11, 12]. This difference in the efficacy could be due to the longer duration of therapy (90 days) in our study compared to previously cited studies (7 – 28 days) [2, 3, 11, 12]. Some authors have reported that a long duration of albendazole may have no additional benefit compared to the short ones [15, 19]. Nevertheless, Garcia et al. (1997) noted a significant difference in the number of cysts persisting at day 360 among patients taking a short (7-day) and long (14-day) schedule of albendazole [7]. An overly-short duration (one week) may not change the natural course of NCC [16]. Our results are supported by another observation [17] and suggest that an extension of the duration of albendazole therapy may be a good choice for patients with NCC.

Results of safety assessment showed that this prolonged regime of albendazole seems to have a favorable safety profile. Liver enzymes were only mildly and temporarily elevated, while urea and creatinine concentrations were within normal limits. The proportion of patients with elevated liver enzymes in our study (>80%) was far higher than that usually reported in those taking albendazole

(10-20%) [14]. A possible reason for this difference was the high rate of patients with increased liver enzymes before therapy (Table 1). Another reason could be the prolonged use of albendazole (90 days) compared to short courses (7 – 28 days) used in most previous studies [2, 3, 11, 12]. Although a high rate of patients with elevated liver enzymes was seen, the proportion of severe elevation was low (1.7%); this is in agreement with a scarcity of reported cases of albendazole-induced liver injury [1, 13,18]. The unchanged levels of urea and creatinine in our patients are similar to other results [17]. During therapy, some patients developed headaches, vomiting, or exacerbation of seizures. These manifestations could be adverse reactions or predictors of drug effectiveness, so they are not included in safety assessments [21].

Some limitations remain in our study. There were only a small number of patients willing to complete treatment and undergo final assessment six months after therapy, so the small sample size is unavoidable. A control group taking placebo drugs is lacking as this is not acceptable practice in our country.

Conclusion

Three 30-day cycles of albendazole appear to have favorable outcomes in patients with neurocysticercosis. Almost all patients had an improvement in cystic lesions and the rate of complete disappearance is encouraging. This regime has good tolerability, but monitoring of liver transaminase levels is critical.

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Conflict of interest

The authors declare that they have no conflict of interests.

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TABLES

Table 1. Baseline patient characteristics (n=60).

Variable		n	% (95% CI)
Age (years, $\overline{X} \pm$ SD)		50.17 ± 10.03	
Gender	Female	8	13.3 (4.8 – 22.2)
	Male	52	86.7 (77.8 – 95.5)
Occupation	Farmer	39	65.5 (52.6 – 77.4)
	Other jobs	21	35.5 (22.6 – 47.4)
Manifestation	Headache	54	90.0 (82.2 – 97.8)
	Seizure	41	68.3 (56.2 – 70.4)
	Memory loss	23	19.2 (12.3 – 34.4)
	Fainting	17	28.3 (16.6 – 40.1)
	Limb numbness	12	20.0 (9.6 – 30.4)
	Vomiting, nausea	9	15.0 (5.7 – 24.3)
	Balance disorders	6	10.0 (2.2 – 17.8)
	Muscle weakness	6	10.0 (2.2 – 17.8)
	Blurred vision	2	3.3 (0.1 – 8.0)
Cyst site*	Hemisphere	50	83.3 (73.6 – 93.0)
	Cortical/ subcortical	25	41.7 (28.8 – 54.4)
	Cerebellum	6	10.0 (2.2 – 17.8)
	Ventricles	1	1.7 (0-0.5)
	Subarachnoid spaces	1	1.7 (0-0.5)
Biochemical parameters	AST (U/L, $\overline{X} \pm$ SD)	38.16 ± 27.45	
	ALT (U/L, $\overline{X} \pm$ SD)	35.87 ± 19.07	

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	Urea (mmol/L, $\overline{X} \pm$ SD)	5.43 ± 1.03
	Creatinine (mmol/L, $\overline{X} \pm$ SD)	80.30 ± 14.12

* same patients with cysts at different sites.

Table 2. Efficacy of antiparasitic treatment (n=60).

	n	% (95% CI)
Cure	26	43.3 (30.4 – 56.2)
Improvement	31	51.7 (38.7 – 64.7)
Inefficacy	3	5.0 (0 – 10.7)

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Table 3. Biochemical parameters before and after therapy (n=60).

Parameters	Course	Before	After	*p-value*
AST (U/L, $\overline{X}$ ± SD)	1	38.16±27.45	72.43± 140.33	0.036
	2	34.20±13.34	54.02 ± 43.81	0.000
	3	39.14±14.44	61.54 ± 64.45	0.003
ALT (U/L, $\overline{X}$ ± SD)	1	35.87±19.07	93.67 ± 110.31	0.000
	2	36.71±17.48	75.91 ± 45.14	0.000
	3	44.63±22.16*	83.30 ± 105.73	0.002
Urea (mmol/L, $\overline{X}$ ± SD)	1	5.43 ± 1.03	5.31 ± 1.12	0.478
	2	5.06 ± 0.62	5.29 ± 0.84	0.023
	3	4.99 ± 0.57	5.48 ± 0.81	0.000
Creatinine (mmol/L, $\overline{X}$ ± SD)	1	80.30 ± 14.12	80.40 ± 10.18	0.946
	2	79.46±8.06	79.19± 8.42	0.746
	3	79.30±7.12	80.78±6.99	0.052

* The mean ALT concentration before the third course was higher than that before the first and the second course ($p<0.001$).

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Running head:

Long course of albendazole for neurocysticercosis

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