

## Original Article

## The efficacy of single-dose albendazole for the treatment of ascariasis

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### ABSTRACT

**Objective** This study aims to assess the efficacy of single-dose albendazole in treating mild, moderate, and severe ascariasis.

**Methods** Stool specimens were collected from randomly selected elementary school children in Suka village, Sumatera Utara, from March to April 2002. Based on the number of eggs per gram feces (NEPG), samples were categorized as mild (NEPG < 7000), moderate (NEPG 7000-35,000), or severe (NEPG > 35,000) ascariasis. All subjects then received 400 mg albendazole orally. NEPG count was repeated on the 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 28<sup>th</sup> day after treatment. The chi-square test was used to compare cure rates between subjects with mild, moderate, and severe ascariasis. The ANOVA and Kruskal-Wallis tests were employed to analyze quantitative data.

**Results** From the 134 specimens collected, we found mild ascariasis in 57 (42.5%), moderate ascariasis in 57 (42.5%), and severe ascariasis in 20 (15%). There was no significant difference between the three groups in NEPG after treatment ( $P > 0.05$ ). The cure rate and egg reduction rate on day 28 after treatment was 100%.

**Conclusion** A single dose of 400 mg albendazole is effective for the treatment of mild, moderate, and severe ascariasis. [Paediatr Indones 2005;45:118-122].

**Keywords:** ascariasis, single-dose albendazole, efficacy

Intestinal helminthiasis is common in the tropics. The high prevalence has been attributed to poor socio-economic state, health education, and personal and environmental hygiene. The World Health Organization reported that there are more than 1 billion cases of soil-transmitted helminthiasis in the world,<sup>1</sup> mostly in children, who also serve as a source of infection.<sup>2</sup> Ascariasis is the most common

form of helminthiasis, with a morbidity of about 250 million. The prevalence of ascariasis in Indonesia is high, particularly among children aged 1–10 years.<sup>3</sup> The parasite is transmitted by swallowing infective eggs from contaminated soil. The larva then matures and mates in the intestine to produce eggs, which are in turn excreted along with feces. This process takes 8–12 weeks. Adult worms can produce up to 27,000,000 eggs.<sup>4</sup> Based on the number of eggs per gram feces (NEPG), the intensity of ascariasis infection is classified into mild (NEPG < 7000), moderate (NEPG 7000-35,000), or severe (NEPG > 35,000).<sup>5</sup>

Albendazole (methyl-5-propylthio-1-H-benzimidazole,  $C_{12}H_{15}N_3O_2S$ ),<sup>6</sup> a new member of the benzimidazole group, has the broadest anthelmintic spectrum. Albendazole and its metabolite, albendazole sulfoxide, inhibit microtubule synthesis in nematodes, irreversibly impairing glucose uptake.

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Excretion of parasites from the gastrointestinal tract may occur up to several days after treatment. The drug also has larvicidal and ovicidal effects.<sup>7</sup> A study in Malawi showed that a single dose of 200 mg albendazole cured 80% of treated elementary school students, a 400 mg dose could cure 85% in another set of subjects, while a 200 mg syrup given to children under 2 years of age cured 83%.<sup>8</sup> Margono<sup>9</sup> gave 400 mg albendazole for three days and achieved a cure rate of 90.01%. Gani<sup>10</sup> and Dewayani<sup>11</sup> both administered a single dose of 400 mg albendazole and achieved cure rates of 83.33%<sup>10</sup> and 99.24%,<sup>11</sup> respectively. When used for 1-3 days, albendazole appeared to be nearly devoid of significant side effects. Mild transient epigastric distress, diarrhea, headache, nausea, dizziness, lassitude, and insomnia have been attributed to the drug in about 6% of patients, but placebo-controlled studies suggested that the incidence of side effects was similar in treatment and control groups.<sup>7</sup>

As of yet, not much is known concerning the efficacy of albendazole in treating severe ascariasis. This study aimed to assess the efficacy of albendazole in treating different intensity levels of ascaris infection.

## Methods

A randomized clinical trial was conducted from March to April 2002 in Suka Village, Tiga Panah Subdistrict, Karo District, Sumatera Utara Province. The study protocol was approved by the Medical Research Ethics Committee of the Medical School, University of Sumatera Utara.

Stools of all elementary school students were collected and examined for ascaris. Of the students who had ascariasis, 134 were randomly selected as subjects. The required sample size was determined using the formula for a relative precision level ( $e$ ) of 15%, 95% confidence interval, and proportion of ascariasis ( $p$ ) of 0.56. The number of eggs per gram feces (NEPG) was examined using the Kato-Katz technique in the Department of Parasitology, Medical School, University of Sumatera Utara. Based on the results, the subjects was categorized into mild (NEPG < 7000), moderate (NEPG 7000–35,000) and severe (NEPG > 35,000) ascariasis. A single dose of 400 mg albendazole was then given.

Stool examinations were repeated on the 7<sup>th</sup>, 14<sup>th</sup>, 21<sup>st</sup> and 28<sup>th</sup> day after treatment to determine the cure rate and egg reduction rate. Efficacy of the drug was determined by its cure rate. A complete cure was recorded when no eggs were detected on a single Kato-Katz smear within one to four weeks after treatment.

Subjects included were elementary school students (grades I-VI) who agreed to participate and had obtained written permission from their parents. The students should be reasonably healthy and should not have taken any anthelmintic for one month before the study commenced. They should not receive other medical or traditional treatments during the study period. Students who suffered from life-threatening diseases other than ascariasis or showed side effects of albendazole were excluded.

The chi-square test was used to compare the cure rates between those with mild, moderate, and severe ascariasis. We used the ANOVA test to analyze quantitative data with normal distribution (homogenous) and the Kruskal-Wallis test to analyze quantitative data with abnormal distribution (non-homogenous) to compare the efficacy of albendazole in the above groups. The result of analysis was considered statistically significant if  $P < 0.05$ . All data were processed using SPSS 11.01 for Windows.

## Results

Of 434 students, 333 had ascariasis, of which 134 were randomly selected as subjects. Of these, 57 had mild ascariasis, 57 had moderate ascariasis, and 20 had severe ascariasis. The students' parents were predominantly farmers with most having an education level of as far as primary school. **Table 1** shows the clinical and laboratory characteristics of the students.

After treatment, there was no significant difference in NEPG between the three groups ( $P = 0.283$ ) (**Figure 1**).

The cure rate after one week of treatment between the three groups showed significant difference. Subjects with mild ascariasis had significantly higher cure rate than those with moderate and severe ascariasis. This difference became insignificant after the second week. Cure rate and egg reduction rate was 100% on day 28 (**Table 2**).

TABLE 1. CLINICAL AND LABORATORY CHARACTERISTICS OF SUBJECTS

Characteristic	Mild ascariasis n = 57	Moderate ascariasis n = 57	Severe ascariasis n = 20
<b>Age (years)</b>			
Mean (SD)	8.8 (1.8)	8.6 (1.8)	8.5 (1.8)
Range	6–12	6–13	7–13
<b>Sex</b>			
Male	30 (52.6%)	30 (52.6%)	8 (40%)
Female	27 (47.4%)	27 (47.4%)	12 (60%)
<b>Body weight (kg)</b>			
Mean (SD)	22.9 (4.2)	23.6 (4.3)	24.6 (4.8)
Range	15–35	16–36.5	19–34
<b>Body height (cm)</b>			
Mean (SD)	119.5 (7.8)	120.9 (8.3)	124.9 (7.0)
Range	104.6–139.9	106.2–138.6	113–136.6
<b>NEPG (SD)</b>	2230.2 (1916.6)	16488.8 (7060.4)	51232.5 (19171.3)

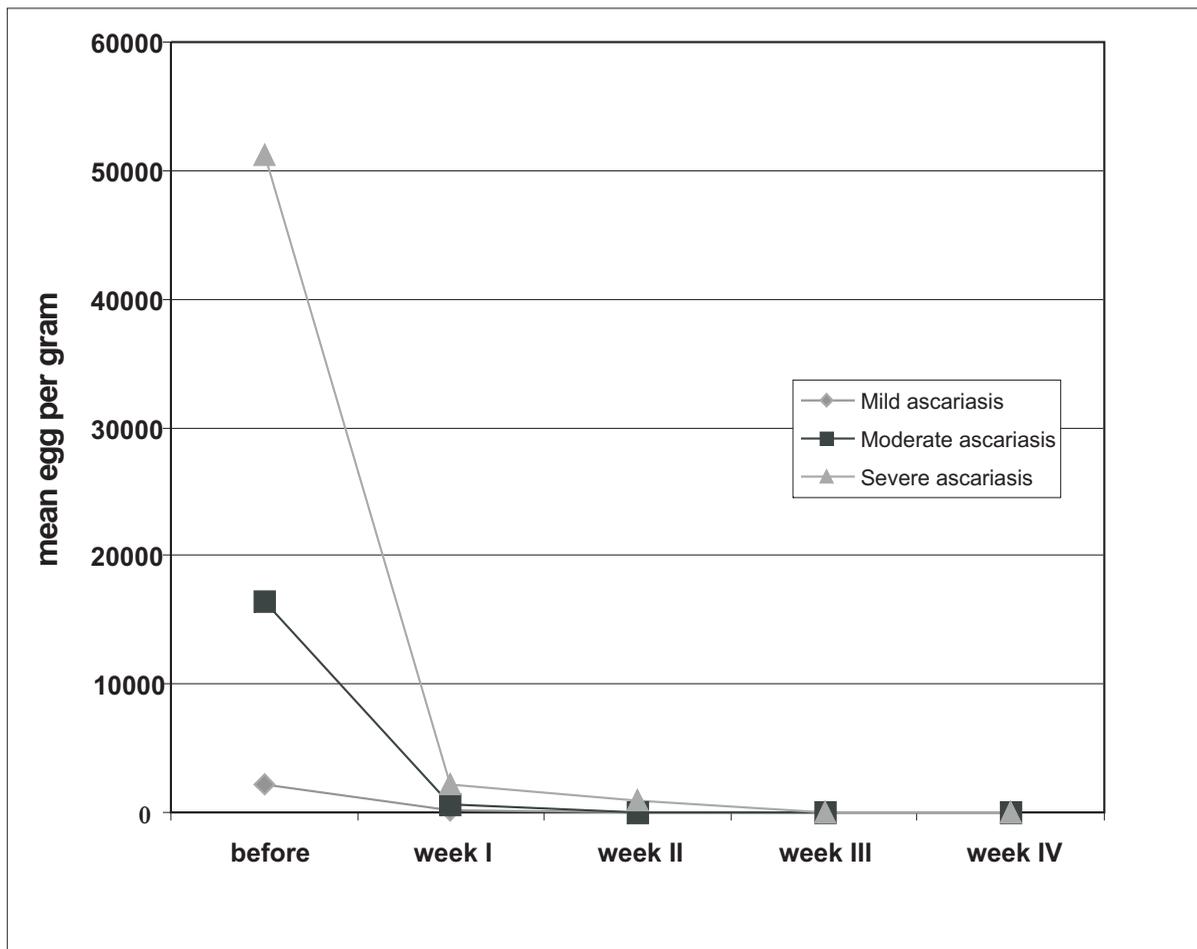


FIGURE 1. MEAN TOTAL *ASCARIS LUMBRICOIDES* EGGS BEFORE AND AFTER TREATMENT

**TABLE 2.** EFFICACY OF ALBENDAZOLE FOR MILD, MODERATE, AND SEVERE ASCARIASIS

Intensity of ascariasis	n	Week I		Week II		Week III		Week IV	
		CR(%)	ERR(%)	CR(%)	ERR(%)	CR(%)	ERR(%)	CR(%)	ERR(%)
Mild	57	77.2	94.5	91.2	99.4	100	100	100	100
Moderate	57	6.1,4	95.9	93.0	99.8	96.5	99.9	100	100
Severe	20	45.0	95.8	90.0	98.4	100	100	100	100

CR : cure rate  
ERR: egg reduction rate

Week I P = 0.022  
Week II P = 0.897

## Discussion

A single dose of 400 mg of albendazole was used in the present study. Of 134 samples, we found mild, moderate, and severe ascariasis in 57 (42.5%), 57 (42.5%), and 20 (15.0%) students, respectively. Norhayati *et al* in a rural district in Malaysia reported that based on the 1987 WHO criteria, mild, moderate, and severe ascariasis were found in 38.96%, 22.08%, and 38.96% of subjects, respectively.<sup>12</sup> Ow-Yang in Kuala Lumpur found that 91.67% of their subjects had mild ascariasis, 5.55% had moderate ascariasis, and 2.78% had severe ascariasis.<sup>13</sup> Gadzer in India reported these proportions to be 16.28%, 79.07%, and 4.65%, respectively,<sup>14</sup> while Misra, also in India, found these to be 73.21%, 23.21%, and 3.57%, respectively.<sup>15</sup> Abadi<sup>16</sup> in Ujung Pandang reported that the proportions of mild, moderate, and severe ascariasis were 73.77%, 14.75% and 11.48%, respectively,<sup>16</sup> while Hadju reported these proportions to be 36.36%, 51.52%, and 12.12%, respectively, among urban slum schoolchildren.<sup>17</sup>

In this study, cure rate and egg reduction rate during the third week were both 100% for mild and severe ascariasis. For moderate ascariasis, these rates were 96.5% and 99.9%, respectively. Our results differed from those of the study by Misra *et al*, which found cure rates of 100% for mild and severe ascariasis and 84.6% for moderate ascariasis, and egg reduction rates of 100% for mild and severe ascariasis and 90.9% for moderate ascariasis.<sup>15</sup> Ow-Yang found that cure rate and egg reduction rate were 50% for moderate ascariasis and 100% for mild and severe ascariasis.<sup>13</sup> Gadzer found that the cure rates were 94.1% for moderate ascariasis and 100% for mild and severe ascariasis.<sup>14</sup> Abadi found that the cure rates were 95.5% for mild ascariasis, 99.8% for moderate ascariasis, and 85.7% for severe ascariasis, and that

egg reduction rates were more than 99.0% in all three groups after 2-4 weeks of treatment.<sup>16</sup> Other investigators such as Alisah *et al*, Ahmad *et al*, and Jongsuksuntigul *et al*, found that the cure rate for ascariasis was 100%.<sup>18-20</sup> A study done by Rahman in Penang showed that overall cure rate one month after treatment was 87.3%, regardless of the intensity of infection.<sup>21</sup> In this study, the cure rate and the egg reduction rate during the fourth week were both 100%.

Based on the children's age, there was no difference in the intensity of infection. Martin *et al* found similar results among children 1-15 years old in Northern Bangladesh.<sup>22</sup> There was no apparent difference in ascariasis by sex in this study. Ozumba reported the same observation in Enugu, Nigeria.<sup>23</sup>

This study suggests that 400 mg of albendazole was equally effective for treating mild, moderate, and severe ascariasis. Ahmad *et al* reported that of 37 patients with ascariasis, 33 were cured by a single dose of 400 mg albendazole and the rest became infection-free by repeating the same dose.<sup>19</sup> Kemp *et al* recommended that 400 mg of albendazole single dose should be given for light infection, but for heavier infection the same dose should be given for three consecutive days.<sup>24</sup>

We found no side effects of albendazole in our subjects, which was similar to findings by Jongsuksuntigul<sup>20</sup> and Fallah.<sup>25</sup>

In conclusion, our study showed that a single dose of 400 mg albendazole was equally effective for mild, moderate, and severe ascariasis.

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