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Effectiveness of Ivermectin treatment among adult patients infected with *Strongyloides stercoralis* in East Gojam zone, Northwest Ethiopia

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Abstract

Introduction Strongyloidiasis caused by the parasite *Strongyloides stercoralis*, is a significant public health issue, particularly in low-income countries with inadequate sanitation practices. Ivermectin is the recommended drug by the World Health Organization for treating *S. stercoralis* infection, but its efficacy in Ethiopia has not been extensively studied. This study aimed to assess the effectiveness of Ivermectin treatment for *S. stercoralis* infection in adult patients.

Methods A cross-sectional study was conducted in government hospitals in northwest Ethiopia from June 2022 to February 2024. A total of 190 patients confirmed to be infected with *S. stercoralis* were treated with Ivermectin (200 µg/kg) for two days. Stool samples were collected two weeks after treatment and analyzed using parasitological concentration techniques.

Results The cure rate was 90% among the treated individuals, demonstrating a significant reduction in the prevalence of *S. stercoralis* infection. Among the cases that were not cured, the majority were older individuals, with a higher proportion (66.8%) residing in rural areas. A small number of non-cured individuals experienced persistent symptoms after treatment. All individuals who successfully cleared the infection were asymptomatic.

Conclusion The study found a 90% cure rate for the current 2-day Ivermectin treatment regimen (200 µg/kg) against *Strongyloides stercoralis* in Ethiopia, suggesting the recommended strategy is appropriate. Age, residential area, and other factors have been found to influence treatment outcomes, warranting further investigation into potential resistance factors and optimizing treatment for different populations.

Keywords Ivermectin, Strongyloidiasis, Ethiopia, Efficacy

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Introduction

Strongyloidiasis, a chronic parasitic infection caused by *Strongyloides stercoralis* and classified as a soil-transmitted helminth, substantially impacts public health. Recent estimates indicate a global burden of approximately 613.9 million cases of strongyloidiasis, primarily concentrated in low-income countries with inadequate personal hygiene, environmental sanitation, and prevalent open-defecation practices, including Ethiopia [1]. This parasitic infection can cause various health complications, resulting in significant mortality [2, 3]. It particularly affects populations in tropical and subtropical regions, especially economically disadvantaged communities [4]. Despite the straightforward treatment for chronic strongyloidiasis, the accurate diagnosis of the infection remains challenging, leading to underestimation its prevalence [5]. In particular, the prevalence of the infection is notable, with school children in Ethiopia experiencing a 15-20.7 prevalence rate [6, 7]. The World Health Organization recommends a preventive chemotherapy strategy utilizing drugs such as mebendazole and albendazole to control soil-transmitted helminth species. However, these chemotherapy drugs exhibit limited effectiveness against *Strongyloides stercoralis* [8, 9].

The World Health Organization further recommends Ivermectin, albendazole, and thiabendazole as the treatments for *Strongyloides stercoralis*. However Ivermectin and thiabendazole have comparable efficacy, though Ivermectin is safer [10, 11]. Hence, the Ethiopian Ministry of Health declared that patients infected with *S. Stercoralis* must be treated with double dose of Ivermectin for two days [12]. However, there is currently a lack of sufficient studies on the efficacy of Ivermectin specifically in Ethiopia. Most of the studies conducted to assess the effectiveness of Ivermectin against strongyloidiasis were single-dose and double-dosages given two weeks apart [13, 14]. This study aimed to evaluate the effectiveness of the double dose of two days Ivermectin treatment for *S. stercoralis* infection.

Methods

Study design, area, and period

A cross-sectional study was conducted from June 1, 2022, to February 2, 2024, from 5 selected Hospitals in the East Gojam zone (which is located between 37°51'0.665″E to 37°42′3.87″E and 11°13′54.246″N to 9°50′19″N), Northwest Ethiopia [15]. Those selected Hospitals were Debre Markos Referral Hospital which serves more than 3.5 million people, Bichena Primary Hospital which serves about 500,000 people, Debre Eliyas Primary Hospital which provides services for about 100,000 people, Lumame Primary Hospital which gives service to about 250,000 people, and Yejube Primary Hospital that provides services for about 200,000 people.

Sample size determination, sampling technique and sampling procedure

The sample size was determined based on a single population proportion formula by considering 95.2% cure rate from previous study [16]. $n = \frac{Z^2 P(1-P)^2}{D^2} = \frac{(1.96)^2 0.952(1-0.952)^2}{(0.03)^2} = 195$, n is sample size, Z is 95% confidence interval, P is prevalence, and D is margin of error. However, 5 recruited individuals didn't complete the study, and 190 sample size was the final sample size.

A convenience sampling technique was used to collect data and stool sample from the total 190 study participants from selected health institutions. From Debre Markos Referral Hospital ($n = 100$), from Bichena Hospital ($n = 30$), from Debre Eliyas Hospital ($n = 15$), from Lumame Hospital ($n = 25$), and Yejube Hospital ($n = 20$) were collected.

Ethical consideration

This research was conducted in compliance with the principles outlined in the Declaration of Helsinki. This study was approved by the Ethics Review Committee of the School of Biomedical and Laboratory Sciences, College of Medicine and Health Sciences, University of Gondar (SBMLS/2853/22). Each participant was thoroughly briefed about the research objective, some participants (who can read and write) signed a written consent form, and others gave oral consent before being enrolled in the investigation.

Eligibility criteria

This study included patients confirmed by routine diagnosis (wet-mounted stool microscopy) as infected with *S. stercoralis*, who were treated with Ivermectin (200 μg/kg) for two days and agreed to provide stool samples after two weeks of treatment. Inclusion criteria were age over 15, signed informed consent, no known underlying chronic health issues, and not taking anthelminthic drugs in the last six weeks. Exclusion criteria were pregnancy and medications with potential interactions.

Data collection and laboratory procedures

A questionnaire (Supplementary 1) was developed by investigators to collect information on the sociodemographic characteristics of the study participants and potential factors that could affect the drug's effectiveness. The data collectors (nurse and laboratory technologists) were trained about the data collection procedures for the questionnaire and stool sample collection, to obtain quality data. The questionnaire was administered to the participants.

Stool Sample collection

Each participant received a clean and leak-proof stool container labeled with their unique identification number. Participants were asked to provide a fresh stool sample of approximately 20 mg. The stool sample was immediately examined at the respective hospital parasitology laboratory. In total, approximately 20 g of fresh stool sample were collected from each of the 190 study participants two weeks after Ivermectin treatment for the diagnosis of *S. stercoralis* using two parasitological concentration techniques: modified formol ether concentration technique (M-FECT) and Baermann concentration technique (BCT).

Modified formol ether concentration technique

Ten milliliter of 0.85% saline was suspended with two grams of fresh feces sample. Two layers of wire mesh were used to strain the suspension into a centrifuge tube. The supernatant was decanted after the centrifugation of the strained suspension for five minutes at 3000 rpm. Then the mixture was thoroughly mixed with 7 ml of 10% formalin and left to stand for 5 min. Three milliliter of diethyl ether was then added. Each tubes were sealed, manually shaken thoroughly for a minute, and centrifuged for five minutes at 3000 rpm. After the debris plug was removed, the top three layers were discarded. Subsequently, the sediment was emulsified with 1 milliliter of 10% formalin added and then examined under a microscope to detect the presence of *S. stercoralis* larvae.

Baermann concentration technique

A large amount of fresh stool sample (approximately 15 g) was mixed with water and 2 g of charcoal powder, then put into a Petri dish covered with a disposable paper towel, and incubated for 24 h at 26 ° C. The incubated stool sample was then suspended in a funnel connected to a plastic tube containing warm water for an hour, allowing the *S. stercoralis* parasites to migrate into the tube. The filtrate in the plastic tube was collected in 15 ml conical test tubes and centrifuged for 5 min at 2000 rpm to separate the parasites from the debris. The supernatant was discarded and the remaining sediment was mixed and examined under a microscope to detect the presence of *S. stercoralis* larvae.

Cure rate determination

The cure rate (CR) for strongyloidiasis resulting from the treatment was determined by dividing the number of individuals who tested negative for *S. stercoralis* larvae after treatment by the number of individuals who tested positive for *S. stercoralis* larvae before treatment. A "cure" was defined as the absence of *S. stercoralis* larvae in stool samples by day two weeks of Ivermectin treatment, while "non-cured" was defined as the presence of *S. stercoralis* larvae two weeks after starting the Ivermectin treatment.

$$CR = \frac{n}{N} \times 100$$

CR = cure rate.

n = number of individuals who tested negative for *S. stercoralis* larvae after treatment.

N = number of individuals who tested positive for *S. stercoralis* larvae before treatment.

Quality control

The study findings were reliable because quality control measures were taken throughout the laboratory procedures. This included pre-analytical, analytical, and post-analytical quality control steps. Each data collection and laboratory processes were conducted under the supervision of the principal investigator. Furthermore, the microscopy result was confirmed by two independent microscopists.

Statistical data analysis

Data were entered and analyzed using IBM SPSS Statistics 25.0. The cure rate for Ivermectin was calculated using descriptive statistics. The association between sociodemographic variables and Ivermectin cure rate was initially assessed using Crude Odds Ratios (COR) in a univariate logistic regression model. Variables with a *p*-value of less than 0.25 in the univariate analysis were then included in a multivariate logistic regression model to calculate Adjusted Odds Ratios (AOR) and identify the variables associated with cure rate within the studied population. In the final model, sociodemographic variables with a *p*-value of less than 0.05 were deemed statistically significant.

Results

Sociodemographic characteristics

A total of 190 patients treated with Ivermectin 200 µg/kg (for two consecutive days) were involved in the study. Of these, 62 were female participants residing in rural areas, while 29 were female participants living in urban areas. Among the male participants, 65 were from rural areas and 34 were from urban areas.

The mean age of the participants was 47.7 years with 19 SD, with a minimum of 15 years and a maximum of 84 years. The sociodemographic characteristics of the participants are presented in Table 1.

Ivermectin effectiveness

Following a two-day Ivermectin treatment, the post-treatment evaluation conducted after 14 days revealed promising results. The cure rate was determined to be

Table 1 Sociodemographic characteristics of patients infected with *S. stercoralis*

Variables	Categories	Frequency(*n*)	Percentage (%)
Sex	Female	91	47.9
	Male	99	52.1
Resident	Rural	127	66.8
	Urban	63	33.2
Age group (years)	15–30	41	21.6
	31–45	52	27.4
	46–60	43	22.6
	>60	54	28.4

n = number of individuals; %=percentage

Table 2 The cure rate of *S. stercoralis-infected* individuals

Variables	Categories	Cured, *n* (%)	Not Cured, *n* (%)	*p*-value
Sex	Male	85(85.8)	14(14.2)	0.047
	Female	86(94.4)	5(5.6)	
Resident	Rural	110(86.6)	17(13.4)	0.027
	Urban	61(96.8)	2(3.2)	
Age group (years)	15–30	40(97.5)	1(2.5)	0.001
	31–45	50(96.2)	2(3.8)	
	46–60	40(93)	3(7)	
	> 60	41(75.9)	13(24.1)	
Total		171(90)	19(10)	

n = number of individuals; %=percentage

Table 3 The effectiveness of Ivermectin treatment on *S. stercoralis* infected patients and associated factors

Variables	Categories	Cureness		COR (95%CI)	*p*-value	AOR (95%CI)	*p*-value
		Cured, n(%*)	Not cured, n(%*)				
Sex	Female	86(50.3)	5(26.3)	1		1	
	Male	85(49.7)	14(73.7)	0.353(0.122, 1.023)	0.055	2.72 (0.884, 8.505)	0.081
Residence	Urban	61(35.7)	2(10.5)	1		1	
	Rural	110(64.3)	17(89.5)	4.714 (1.054, 21.037)	0.043	0.171 (0.036, 0.810)	0.026**
Age group (years)	15–30	40(23.4)	1(5.3)	1		1	
	31–45	50(29.2)	2(10.5)	0.079 (0.10, 0.631)	0.017	1.342 (0.115, 15.679)	0.815
	46–60	40(23.4)	3(15.8)	0.126 (0.027, 0.591)	0.009	3.045 (0.296, 31.330)	0.349
	> 60	41(24.0)	13(68.4)	0.237 (0.063, 0.891)	0.033	12.125 (1.476, 99.585)	0.02**

n = number of individuals; %*=percentage with in outcome variable; **=statistically significant, $p < 0.05$; COR = crude odds ratio; AOR = adjusted odds ratio; CI = confidence interval

90%, indicating a significant reduction in the prevalence of the infection (Table 2).

Among the non-cured cases 10% (19/190), consisting of 14 males and 5 females, the majority (13/19) were over 60 years old. The remaining non-cured participants were aged 15–30 ($n = 1$), 31–45 ($n = 2$), and 46–60 ($n = 3$). Most of the noncured individuals (17/19) are rural residents. Only a small proportion (2/19) of noncured individuals experienced persistent signs and symptoms (abdominal discomfort and nausea) after Ivermectin treatment, they were rural residents, and all individuals cleared from *S. stercoralis* were asymptomatic.

Associated factors affecting Ivermectin efficacy

The findings of this study demonstrate a significant correlation between the age of infected individuals and the efficacy of Ivermectin. The effectiveness of Ivermectin decreased in individuals older than 60 years about 12 times more likely to be unable to cure ($p = 0.02$) than in young adults under 30 years. Similarly, patients from rural areas are 2.7 times more likely not to be cured than those from urban residents ($p = 0.026$, 95% CI 0.04–0.8) (Table 3).

Discussion

The present research aimed to assess the effectiveness of Ivermectin treatment (200 g/kg) administered for two consecutive days against strongyloidiasis in patients older than 15 years, from East Gojam, Ethiopia. Evaluation of the effectiveness of Ivermectin revealed promising results. A post-treatment assessment after 14 days showed a high cure rate (90%). This indicates a significant

reduction in the prevalence of strongyloidiasis among the treated participants. This result was comparable with a study that recorded 88.9% in Thailand [17]. However, the efficacy result of the current study was lower than the single dose of Ivermectin in school children (94.6%) in the Amhara region, Ethiopia [6]; single dose (96.8%), and double dose Ivermectin (93.1%) in Thailand [14]. This result would be because the number of older (>60 years) participants in this study is comparably higher (54/190), and mostly the older individuals would have deprived immunity to clear parasitic infection [18]. Additionally, this ineffectiveness could be due to the autoinfection cycle of the parasite, which can be completed within 3 to 4 weeks in human tissues, as well as the poor immune system function of the infected individuals [19].

The age distribution of the participants showed a diverse range, with individuals ranging from 14 to 84 years old. The mean age of the participants was 44.6 ± 19.4 SD years, indicating that all age groups are vulnerable to this soil-transmitted helminthic infection. The age distribution was relatively balanced between different age groups for both women and men, with a slightly higher number of participants below the age of 30.

This study showed that more non-cured individuals (17/19) were rural residents, which was 13.4% of the rural resident infected persons; this indicated that those rural resident individuals might not take the 2nd -day Ivermectin drug and they may neglect modern treatment regimen [20]. However, these individuals remained asymptomatic (except 2 individuals), suggesting that Ivermectin may still provide some benefit in reducing the clinical impact of the infection.

Among non-cured cases (10% of the total), the majority (13/19) were over 60 years of age, indicating a potential association between age and treatment outcomes. Only a few non-cured participants were aged 15–60 ($n=6$), suggesting that age may play a role in treatment response The cause for the older age groups being more likely not to be cured could be the immune status of the older people more likely to be lower than the younger populations [21] as immunity of the infected individual is important for the clearance of the parasite [22, 23].

Conclusion and recommendation

The study found that the current two-day Ivermectin treatment regimen (200 µg/kg) was highly effective against *Strongyloides stercoralis* infection, with a cure rate of 90% among adult patients in the East Gojam zone of Northwest Ethiopia. This high treatment success rate suggests that the current Ivermectin-based treatment strategy recommended by the Ethiopian Ministry of Health is appropriate for reducing strongyloidiasis in the study area. The study also identified that age and residential area influence the treatment outcome.

Moreover, a higher proportion of non-cured individuals resided in rural areas, suggesting the need for further investigation into potential factors such as variations in parasitic strains that might contribute to treatment resistance, and other factors that influence treatment response. This will help to optimize treatment strategies for different patient populations, as well as evaluate the long-term effectiveness and potential adverse effects of Ivermectin treatment.

Supplementary Information

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Supplementary Material 1

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Author contributions

Conceptualization: GAA; Data curation: GAA, AA; Formal analysis: GAA, AA, YMW; Investigation GAA, AA, MB; Methodology: GAA, AA, YM, KM, AF, AS; Resources GAA, YM, AS; Software: GAA, AA, HB, AM, MG; Supervision YM, MJ, MG, MB, AF; Validation: AA, YM, KM, MJ; Writing original draft: GAA, AA. All Authors approved the final version of the manuscript.

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Data availability

The datasets used and analyzed during the current study are in the manuscript and available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was approved by the Ethics Review Committee of the School of Biomedical and Laboratory Sciences, College of Medicine and Health Sciences, University of Gondar (SBMLS/2853/22). Support letters and permission were obtained from the respective hospitals as well. Each participant signed a written consent form and gave oral consent before the investigation.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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