



Safety and Efficacy Triple Drug Therapy (IDA) versus Two-drug therapy DA in Lymphatic Filariasis: A Systematic Review

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ABSTRACT

Lymphatic filariasis (elephantiasis) is a parasitic disease caused by *Wuchereria bancrofti*, *Brugia malayi*, and *Brugia timori*, and is transmitted through the bite of infected mosquitoes. This disease is classified as a neglected tropical disease and has been targeted for global elimination through mass drug administration strategies. This systematic review aimed to evaluate the safety and effectiveness of a single-dose triple-drug therapy consisting of ivermectin, diethylcarbamazine, and albendazole (IDA) compared with the two-drug regimen of diethylcarbamazine and albendazole (DA) based on randomized clinical trials. A literature search was conducted in PubMed using the keyword "elephantiasis," yielding eleven relevant studies published within the last five years. The results indicated that moderate adverse events occurred more frequently with IDA therapy, although most were mild in nature, while serious adverse events were more commonly reported with DA therapy. No significant differences were observed in filarial antigen levels between the groups. IDA therapy was well tolerated and considered as safe as DA, while demonstrating greater effectiveness in clearing microfilariae. With high coverage of mass drug administration, widespread use of IDA has the potential to accelerate the elimination of lymphatic filariasis.

Keywords: Lymphatic, Filariasis, Mass Drug Administration, Elephantiasis, Ivermectin.

ABSTRAK

Filariasis limfatik (elefantiasis) merupakan penyakit parasit yang disebabkan oleh *Wuchereria bancrofti*, *Brugia malayi*, dan *Brugia timori*, serta ditularkan melalui gigitan nyamuk yang terinfeksi. Penyakit ini termasuk penyakit tropis terabaikan dan menjadi target eliminasi global melalui strategi pemberian obat massal. Tinjauan sistematis ini bertujuan mengevaluasi keamanan dan efektivitas terapi tiga obat tunggal ivermektin, dietilkarbamazin, dan albendazol (IDA) dibandingkan terapi dua obat dietilkarbamazin dan albendazol (DA) berdasarkan uji klinis acak. Penelusuran literatur dilakukan di PubMed menggunakan kata kunci elephantiasis dan menghasilkan sebelas studi relevan dalam lima tahun terakhir. Hasil menunjukkan bahwa efek samping sedang lebih sering terjadi pada terapi IDA, namun sebagian besar bersifat ringan, sedangkan efek samping serius lebih banyak ditemukan pada terapi DA. Tidak terdapat perbedaan bermakna pada kadar antigen filaria antar kelompok. Terapi IDA dapat ditoleransi dengan baik dan dinilai sama amannya dengan DA, serta lebih efektif dalam membersihkan mikrofilaria. Dengan cakupan pemberian obat massal yang tinggi, penggunaan luas terapi IDA berpotensi mempercepat eliminasi filariasis limfatik.

Kata Kunci: Filariasis Limfatik, Pemberian Obat Massal, Elefantiasis, Ivermektin.

INTRODUCTION

Lymphatic filariasis, also known as elephantiasis, is a parasitic infection caused by the nematode worms *Wuchereria bancrofti*, *Brugia malayi*, and *Brugia timori*, which are transmitted to humans through the bites of infected *Aedes*, *Culex*, *Anopheles*, and *Mansonia* mosquitoes (Azhar et al., 2023; Yadav, Yadav, & Alam, 2024). Globally, lymphatic filariasis is classified as a neglected tropical disease (NTD), a group of chronic infections that predominantly affect low-income countries and significantly impair educational attainment, workforce participation, social inclusion, and economic productivity, thereby perpetuating cycles of poverty and stigma (Sinha et al., 2023; Bagonza et al., 2025).

The adult filarial worms inhabit the human lymphatic system, which plays a crucial role in maintaining fluid balance and immune defense. Transmission occurs when mosquitoes ingest microfilariae during blood meals and subsequently transmit infective larvae to other individuals. The most severe clinical manifestation of lymphatic filariasis is elephantiasis, characterized by chronic, progressive, and often irreversible swelling of the limbs and genital organs (Ton et al., 2015). Affected individuals may suffer from lymphedema, hydrocele, and recurrent acute dermatolymphangioadenitis, conditions that cause not only physical disability but also profound psychosocial distress and economic burden (Debrah et al., 2006). Consequently, lymphatic filariasis is recognized as one of the leading causes of permanent disability worldwide (Lee & Ryu, 2019).

Lymphatic filariasis is one of the oldest known parasitic diseases and, although rarely fatal, results in long-term disability with significant social and economic consequences (Medeiros et al., 2022). Currently, more than 120 million people in 81 countries are infected globally, and over one billion individuals live in areas at risk of transmission (Lee & Ryu, 2019). In Indonesia, lymphatic filariasis remains a major public health concern despite elimination efforts initiated in 1975, particularly in highly endemic regions. Indonesia is unique as the only country where all three filarial species are endemic (*W. bancrofti*, *B. malayi*, and *B. timori*), with the majority of infections attributed to *B. malayi* (Astuti et al., 2023). In 2016, it was estimated that 29 provinces and 239 districts were endemic for lymphatic filariasis, placing more than 102 million individuals at risk of infection.

According to the Indonesian Ministry of Health, approximately 125 million Indonesians representing about 9% of the global population at risk remain vulnerable to lymphatic filariasis, with the highest prevalence observed in eastern provinces such as Maluku, Papua, West Papua, East Nusa Tenggara, and North Maluku (Tan et al., 2014). Transmission requires repeated mosquito bites over extended periods, making individuals living long-term in endemic tropical and subtropical regions particularly susceptible, while short-term travelers face minimal risk. Although many infections remain asymptomatic for years, progressive lymphatic damage may eventually result in severe morbidity, including lymphoedema, elephantiasis, hydrocele, and other less common manifestations such as breast lymphoedema and vulvar swelling (Medeiros et al., 2022). Disease progression is influenced by complex interactions involving adult parasites, host immune responses, *Wolbachia* endosymbionts, and secondary bacterial or fungal infections (Babu & Nutman, 2012).

To address the global burden of lymphatic filariasis, the World Health Organization (WHO) launched the Global Programme to Eliminate Lymphatic Filariasis (GPELF) with the goal of eliminating the disease as a public health problem through mass drug administration (MDA) (World Health Organization, 2010; Goss et al., 2019; World Health Organization, 2020). The primary strategy involves administering combinations of antifilarial drugs albendazole with either ivermectin or diethylcarbamazine, to reduce microfilarial density to levels insufficient to sustain transmission (Irvine et al., 2017; Gyapong et al., 2018). Successful implementation of MDA depends not only on drug efficacy but also on community acceptance, individual perceptions, and treatment adherence (Krentel et al., 2021).

Recent evidence suggests that triple-drug therapy consisting of ivermectin, diethylcarbamazine, and albendazole (IDA) may offer superior efficacy compared to the standard two-drug regimen of diethylcarbamazine and albendazole (DA). However, evidence comparing the safety and efficacy of IDA versus DA remains limited, particularly in Indonesia and other tropical endemic countries. Therefore, this systematic review aims to evaluate and compare the

safety and efficacy of IDA and DA regimens in the treatment and elimination of lymphatic filariasis based on available randomized clinical trial evidence.

RESEARCH METHODS

This study was conducted as a systematic review to evaluate research related to elephantiasis. A comprehensive literature search was performed using the PubMed database with the keyword “elephantiasis”. The initial search identified 4,112 publications related to the topic. The retrieved records were screened based on study design, and 91 publications employing a randomized clinical trial (RCT) methodology were identified. Further screening was conducted by applying a publication time restriction, limiting the selection to studies published within the last five years. After this eligibility assessment, 11 full-text articles met the inclusion criteria.

A more detailed evaluation of methodological quality and relevance to the research objectives was subsequently performed. As a result, 3 studies were deemed eligible and included in the final systematic review. The inclusion criteria were: (1) original research articles with a randomized clinical trial design, (2) studies focusing on elephantiasis, (3) publications within the last five years, and (4) availability of full-text articles. The exclusion criteria included review articles, case reports, editorials, conference abstracts, and studies with incomplete or irrelevant data.

Data were extracted systematically from the included studies, including author information, year of publication, study design, participant characteristics, interventions, and main outcomes. The results were synthesized using a descriptive and narrative approach.

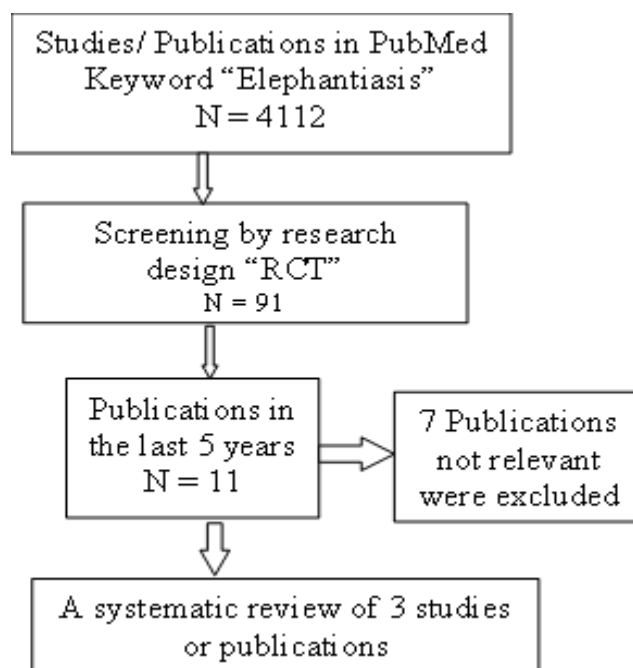


Figure 1. PRISMA flow diagram of the study selection process.

RESULTS

Table 1. Summary of three selected articles.

Aspect	Weil et al. (2019)	King et al. (2018)	Dubray et al. (2020)
Title	The safety of double-and triple-drug community mass drug administration for lymphatic filariasis: A multicenter, open-label,	A Trial of a Triple-Drug Treatment for Lymphatic Filariasis	Safety and efficacy of co-administered diethylcarbamazine, albendazole and ivermectin during mass drug administration for lymphatic filariasis in Haiti: Results

	cluster-randomized study		from a two-armed, open-label, cluster-randomized, community study
Study Design	Community-based, open-label, cluster-randomized, multicenter	Randomized, double-blind clinical trial	Community-based, open-label, cluster-randomized
Location	Papua New Guinea, Indonesia, Haiti, India	Haiti, India, Indonesia, Papua New Guinea	Haiti
Interventions	1. IDA: Ivermectin + Diethylcarbamazine (DEC) + Albendazole 2. DA: DEC + Albendazole	1. IDA: Ivermectin + DEC + Albendazole 2. DA: DEC + Albendazole	1. IDA: Ivermectin + DEC + Albendazole 2. DA: DEC + Albendazole
Population & Sample	> 26,000 participants from endemic communities	182 participants with microfilaremia (active infection)	2,753 participants from 32 clusters
Primary Objective	To compare the safety of IDA vs. DA regimens during MDA at the community level.	To compare the efficacy of IDA vs. DA regimens in clearing microfilaremia.	To assess the safety and efficacy of IDA vs. DA regimens in a large-scale MDA setting.
Safety Results (Adverse Events)	- IDA: 26.3% experienced systemic adverse events. - DA: 14.7% experienced systemic adverse events. - Adverse events in the IDA group were more frequent but mostly mild-moderate and transient. Local reactions were less common.	- Adverse events were more frequent in the IDA group (69% vs 55%). - Common reactions: muscle pain, fever, headache, malaise. - Most reactions were mild to moderate and transient.	- IDA: 31.7% experienced adverse events. - DA: 15.2% experienced adverse events. - Adverse events were more common in the IDA group, especially systemic ones, but serious events were rare.
Efficacy Results	- The IDA regimen was more effective in suppressing microfilaremia prevalence compared to DA at 12 months post-MDA.	- IDA was significantly more effective at clearing microfilaremia up to 36 months compared to DA. - At 36 months, clearance rate for IDA: 91.2% vs DA: 55.7%.	- IDA was significantly more effective at reducing microfilaremia prevalence compared to DA. - Reduction in microfilaremia prevalence was greater in IDA clusters.
Key Conclusion	The IDA regimen has an acceptable safety profile and is more effective than DA for LF MDA, supporting its use in elimination programs.	The triple-drug IDA regimen is more effective than the double-drug DA regimen in clearing microfilaremia and preventing relapse in infected individuals.	This study supports the use of IDA as a safe and highly effective regimen for MDA in LF-endemic areas, such as Haiti.

Dubray et al. reported that 96.0% (5,761/5,998) of treated participants were followed for safety at least once during the 7-day post-treatment period, including 2,917 participants who received ivermectin, diethylcarbamazine, and albendazole (IDA) and 2,844 who received diethylcarbamazine plus albendazole (DA). Overall, 14.1% (812/5,761) of participants reported at least one adverse event (AE), with a low intracluster correlation coefficient (ICC = 0.02). Unexpectedly, AEs were more frequently reported in the DA group (17.3%, 491/2,844) than in the IDA group (11.0%, 321/2,917). Most AEs were mild, accounting for 88.7% of AEs in the DA arm and 93.4% in the IDA arm. AEs were reported more frequently by women than men in both treatment arms, and adults aged ≥ 18 years reported more AEs (17.9%) than participants < 18 years (10.1%) (Dubray et al., 2020).

No serious adverse events (SAEs) occurred following IDA treatment. In contrast, three SAEs (0.1%) were reported after DA treatment, involving hospitalization for evaluation of conditions including hypertension, urinary tract infection, anemia, dysuria, nausea, vomiting, fever, and abdominal pain. All SAEs resolved within 48 hours. Two SAEs were considered possibly related to treatment, and one was considered probably related (Dubray et al., 2020).

AEs were more common among participants with microfilaremia; however, AE rates among microfilaremic individuals were similar between IDA (34.1%) and DA (39.4%). Pretreatment microfilarial (Mf) counts were significantly higher among participants who experienced AEs compared to those who did not (20.98 vs. 8.81 Mf/mL, $P = 0.002$). Multivariable logistic regression analysis demonstrated a significantly lower risk of AEs among participants receiving IDA compared to DA after adjusting for age, sex, and infection status (Dubray et al., 2020).

The most frequently reported AEs across both treatment arms were headache, abdominal pain, and dizziness. Scrotal AEs were reported by 1.3% of men and were significantly more common following DA than IDA and among Mf-positive men. Most scrotal AEs were mild (grade 1), with higher-grade events observed only in the DA arm (Dubray et al., 2020).

Similar findings were reported by Weil et al., where approximately 97.4% of participants were assessed within two days of treatment. Overall AE rates were comparable between IDA (12.0%) and DA (12.1%), with no significant differences in severity. AE rates were higher among participants with microfilaremia, particularly those with higher pretreatment Mf counts (Weil et al., 2019).

King et al. reported that most AEs following IDA were mild or moderate. One severe AE (grade 3) occurred in a participant with high baseline Mf counts and resolved with supportive treatment. Logistic regression analysis showed that the odds of grade 2 AEs increased with rising Mf density (King et al., 2018).

Regarding efficacy, Dubray et al. found no significant difference between treatment arms in the proportion of circulating filarial antigen (CFA)-positive participants who became CFA-negative one year after treatment (IDA: 20.5%; DA: 25.6%; $P = 0.3$). Reductions in filarial test strip (FTS) scores were observed in both groups, with no significant between-group differences at follow-up visits (Dubray et al., 2020).

In contrast, IDA demonstrated superior efficacy in clearing microfilaremia. One year after treatment, 94.4% of participants receiving IDA became Mf-negative compared to 75.9% in the DA group ($P = 0.02$). Mean Mf counts significantly decreased in the IDA arm but not in the DA arm (Dubray et al., 2020).

King et al. similarly reported that a single dose of IDA was more effective in clearing *Wuchereria bancrofti* microfilariae than a single dose or repeated annual doses of DA. Clearance of microfilaremia persisted for at least 36 months in most participants treated with IDA, and residual Mf levels were reduced to levels unlikely to sustain transmission (King et al., 2018).

DISCUSSION

The findings from multiple studies consistently demonstrate that the triple-drug regimen IDA is safe, well tolerated, and at least as safe as the standard two-drug DA regimen in diverse lymphatic filariasis–endemic settings. Although adverse events were common following both regimens, the vast majority were mild, and serious adverse events were rare, occurring more frequently after DA than IDA (Dubray et al., 2020; Weil et al., 2019).

A key determinant of AE occurrence across studies was baseline microfilarial density. Participants with higher Mf counts were more likely to experience AEs, particularly moderate events, regardless of treatment regimen. This finding supports the biological mechanism whereby rapid killing of microfilariae triggers inflammatory responses, explaining the higher AE frequency observed in individuals with microfilaremia (King et al., 2018).

Importantly, IDA demonstrated superior efficacy in clearing microfilaremia compared to DA, with sustained reductions observed up to 36 months after treatment. Although both regimens reduced circulating filarial antigen levels, complete antigen clearance was uncommon following a single treatment dose, suggesting partial macrofilaricidal effects consistent with previous evidence (King et al., 2018). The addition of ivermectin appears to enhance sterilization of adult worms and significantly accelerate microfilarial clearance, thereby reducing transmission potential.

From a public health perspective, these findings are highly relevant for mass drug administration programs. The low incidence of serious adverse events, particularly after IDA, meets WHO safety requirements for policy adoption. Furthermore, the superior microfilarial clearance achieved with IDA suggests that its widespread implementation could substantially accelerate the elimination of lymphatic filariasis, especially in settings with low to moderate infection prevalence (Weil et al., 2019).

Overall, the evidence supports the use of IDA as a safe and more effective alternative to DA for lymphatic filariasis elimination, provided that adequate community engagement and treatment coverage are achieved.

CONCLUSION

Based on the findings of this systematic review, the triple-drug regimen consisting of ivermectin, diethylcarbamazine, and albendazole (IDA) is safe, well tolerated, and at least as safe as the standard two-drug regimen diethylcarbamazine plus albendazole (DA) for the treatment of lymphatic filariasis. Most adverse events reported after both treatment regimens were mild and self-limiting, with serious adverse events being rare and occurring more frequently following DA than IDA.

Baseline microfilarial density was identified as a key factor influencing the occurrence of adverse events, with higher microfilarial counts associated with increased risk, regardless of treatment regimen. Importantly, IDA demonstrated superior effectiveness in clearing microfilaremia compared to DA, with sustained reductions observed over long-term follow-up, while both regimens showed comparable and partial effects on circulating filarial antigen levels.

Overall, the evidence indicates that IDA provides a favorable balance between safety and enhanced efficacy, supporting its use as a mass drug administration regimen. With adequate treatment coverage and community acceptance, the widespread implementation of IDA has strong potential to accelerate the elimination of lymphatic filariasis in endemic settings.

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