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Safety and Efficacy of Dihydroartemisinin-Piperaquine for Intermittent Preventive Treatment of Malaria in Pregnancy: A Systematic Review of Randomized Controlled Trials

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ABSTRACT

Preventing malaria in pregnant women is crucial, especially for the safety of both the mother and the baby, particularly in malaria-endemic areas. Dihydroartemisinin-Piperaquine (DHP) is one of the options for Intermittent Preventive Treatment in pregnancy (IPTp). Although several previous studies have assessed DHP as a preventive antimalarial in pregnancy, this study systematically consolidates the most recent Randomized Controlled Trials (RCTs), reflecting new evidence and resistance trends to Sulfadoxine-Pyrimethamine (SP) across malaria-endemic regions. This study aims to review the safety and efficacy of DHP use during pregnancy. The methodology involved a comprehensive literature search from the databases PubMed, ScienceDirect, Google Scholar, and Cochrane, published in English from 2020 to 2024. Inclusion criteria encompassed double-blind RCT evaluating the use of DHP during pregnancy. Exclusion criteria included studies that did not involve pregnant women, did not use DHP, and study designs other than double-blind RCT. The initial search yielded 255 articles. After screening for duplicates, a total of 50 duplicates were removed. Ultimately, 5 articles were identified after screening titles, abstracts, and full texts. The analysis results indicate that IPTp DHP is more effective in reducing the incidence of malaria compared to IPTp SP. However, IPTp SP is safer to use than IPTp DHP due to fewer adverse effects. The use of DHP may be considered for IPTp in cases of SP resistance. This review provides an updated synthesis of recent RCTs focusing on the comparative safety and efficacy of DHP versus SP in IPTp of malaria in pregnancy, highlighting recent evidence in the context of emerging SP resistance.

***Keywords*:** Malaria, Pregnancy, Intermittent preventive treatment, Dihydroartemisinin-piperaquine, Randomized controlled Trial

INTRODUCTION

Malaria is a treatable parasitic disease; however, it poses a life-threatening risk, with acute fever being one of the most common symptoms.[1] The causative agent is the female Anopheles mosquito.[2] There are 120 known species of *Plasmodium*, but only five can cause malaria infections in humans: *Plasmodium falciparum*, *Plasmodium vivax*, *Plasmodium ovale*, *Plasmodium malariae*, and *Plasmodium knowlesi*. Among these, *Plasmodium falciparum* is responsible for approximately 99% of malaria-related deaths worldwide[3,4] The parasite invades the host's red blood cells and degrades hemoglobin within the vacuole.[5]

Plasmodium falciparum is responsible for the majority of malaria cases in Africa

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(>99%), the Western Pacific (71.9%), the Eastern Mediterranean (69%), and Southeast Asia (62.8%).[3] Indonesia is an endemic region for malaria, with over 90 million people residing in malaria-endemic areas[6] In 2023, Indonesia reported 418,546 cases of malaria.[7] Malaria is still one of the disease with the highest incidence in Indonesia.[8,9]

Pregnant women and young children (under the age of 5) are at high risk of malaria infection, with approximately 10,000 women and 200,000 infants dying each year due to malaria during pregnancy.[10] Malaria in pregnancy can lead to placental malaria, where erythrocytes infected with *P. falciparum* adhere to placental receptors, triggering inflammation and damage to the placenta, which poses a risk to both the mother and the infant.[11]

Rapid diagnosis and treatment of malaria infection, whether symptomatic or asymptomatic, are essential to prevent severe disease in both mothers and infants.[12] Malaria during pregnancy can pose a significant threat to mothers, unborn children, and neonates, including the risk of mortality.[13] Maternal anemia, fetal loss, and low birth weight can occur as a result.[14]

Dihydroartemisinin-piperaquine (DHP) is the first-line treatment for uncomplicated malaria in Indonesia.[15] DHP serves as an alternative medication for intermittent preventive treatment, particularly in conditions with high resistance to sulfadoxine-pyrimethamine (SP), especially during weeks four to six after administration.[16] The use of DHP as a preventive measure has been shown to be effective in malaria prevention with a good safety profile.[17] DHP effectively eliminates malaria parasites due to the long half-life of piperaquine, providing prophylaxis even after treatment.[15]

The distribution of DHP for malaria during the second and third trimesters is associated with a reduction in adverse effects for both mothers and infants.[18] DHP presents a promising alternative to SP due to its rapid parasiticidal action and the long half-life of piperaquine.[19] The use of DHP for malaria prevention is an acceptable strategy during pregnancy when compared to SP and is considered an effective antimalarial option in cases of resistance.[20] Notably, resistance to SP is more frequently observed in pregnant women than in the general population.[21]

Data regarding the safety and efficacy of DHP as a preventive measure for malaria during pregnancy remains limited. This study aims to review the safety and efficacy of DHP during pregnancy through a systematic review of recent randomized controlled trials.

METHODS

Study Type

This study is a systematic review of RCTs conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA 2020) guidelines. The review aimed to identify, evaluate, and synthesize existing evidence on the safety and efficacy of Dihydroartemisinin-Piperaquine (DHP) as intermittent preventive treatment in Pregnancy (IPTp)

Systematic Search of Literature

A comprehensive search was conducted in databases using PubMed, ScienceDirect, Google Scholar, and Cochrane. Articles included were double-blind randomized controlled trials published in English from January 1, 2020 to September 30, 2024. The keywords used for searching articles were "Dihydroartemisinin-Piperaquine in Pregnancy." The database search yielded 255 articles. Additional references were obtained from the references provided in the articles identified through the search.

Inclusion and Exclusion Criteria

Inclusion criteria were analyzed from research articles with a study design of double-blind randomized controlled trials on the use of dihydroartemisinin-piperaquine (DHP) in pregnancy. The exclusion criteria included individuals

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who were not pregnant, did not use DHP, and studies that were not designed as double-blind randomized controlled trials.

Research Procedure

The initial step of this study involved identifying and collecting articles from the designated databases. The collected articles were then filtered to remove duplicates from each database, followed by screening based on titles and abstracts. The next phase involved full-text screening to obtain the inclusion criteria.

Data Extraction

Data extraction was performed using Excel software, focusing on the authors, year of publication, country, study design, number of subjects, outcomes, and effect sizes. This review centers on the efficacy and safety of DHP in pregnancy. The inclusion and exclusion criteria, along with the data extraction process, are detailed in Figure 1. The main findings and conclusions drawn from all reviewed articles based on the topics and key parameters of this research are summarized in Table 1.

Measurement and Assessment of Effect

The following outcomes were extracted and analyzed, efficacy outcomes; incidence of maternal malaria infection, placental malarian, and clinical malaria during pregnancy. Safe outcomes; maternal adverse effect and fetal/neonatal outcomes. For each study, details on the intervention regimen, comparator group, sample size, and follow-up duration were recorded. The effect measures included relative risk (RR), odds ratio (OR), or hazard ratio (HR) with 95% confidence interval (Cis) as reported by the original studies.

Statistical Analysis

No quantitative meta-analysis was performed; instead, a qualitative descriptive synthesis was conducted. Heterogeneity was assessed narratively, considering study design, sample size, and regional malaria endemicity. The main findings were tabulated to present comparative trends in safety and efficacy between DHP and SP.

RESULTS AND DISCUSSION

Study Selection

A total of 255 articles were initially identified through database searches. After the removal of 50 duplicate records, 205 studies remained for title and abstract screening. Of these, 118 articles were excluded for the following reasons. A total of 87 full-text articles were then reviewed for eligibility. Following the application of inclusion and exclusion criteria, only 5 randomized controlled trials (RCTs) met the inclusion criteria and were included in the final analysis (Figure 1) and will be discussed in Table 1.

Efficacy of Dyhidroartemisin-Piperaquine (DHP)

The efficacy results can be observed in Table 2. A study conducted in Malawi in 2019,[22] examined the differences in effects of administering IPTp (Intermittent Preventive Treatment in Pregnancy) with SP, DHP, and DHP+AZ in pregnant women, revealing that fetal growth outcomes were superior with IPTp SP compared to IPTp DHP.

SP works by inhibiting folate synthesis in malaria parasites, effectively reducing parasitemia levels. This reduction also helps prevent anemia in pregnant women. Although DHP is superior in clearing malaria parasites, its dual action may be more intense and could lead to greater disruptions in maternal physiology, including glucose metabolism. This, in turn, may indirectly affect fetal growth, as glucose is a primary nutrient for the developing fetus. Additionally, SP dosages have been shown to effectively reduce placental malaria without disrupting maternal metabolism, thereby helping pregnant women maintain nutritional status, which is critical for optimal fetal growth.[23] In 2020, a similar study was conducted by[24] examining the differences in the effects of IPTp using SP and DHP in Maiduguri, Nigeria.

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This study found no significant difference between the two treatments concerning the incidence of placental malaria (IPTp DHP 56.2% and IPTp SP 52.8%). DHP is highly effective in treating uncomplicated falciparum infections, with a cure rate exceeding 96%.[25]

On the other hand, there has been a development of resistance of malaria parasites to SP in several regions.[24] According to WHO protocols, SP is no longer effective for use in intermittent preventive treatment for pregnant women and infants in most areas of East and Central Africa.[26] Thus, IPTp DHP can serve as a safe and well-tolerated alternative.[24]

DHP has a very high efficacy as IPTp for malaria during pregnancy.[19] DHP possesses superior antimalarial properties compared to sulfadoxine-pyrimethamine (SP) in reducing the incidence of malaria.[22]

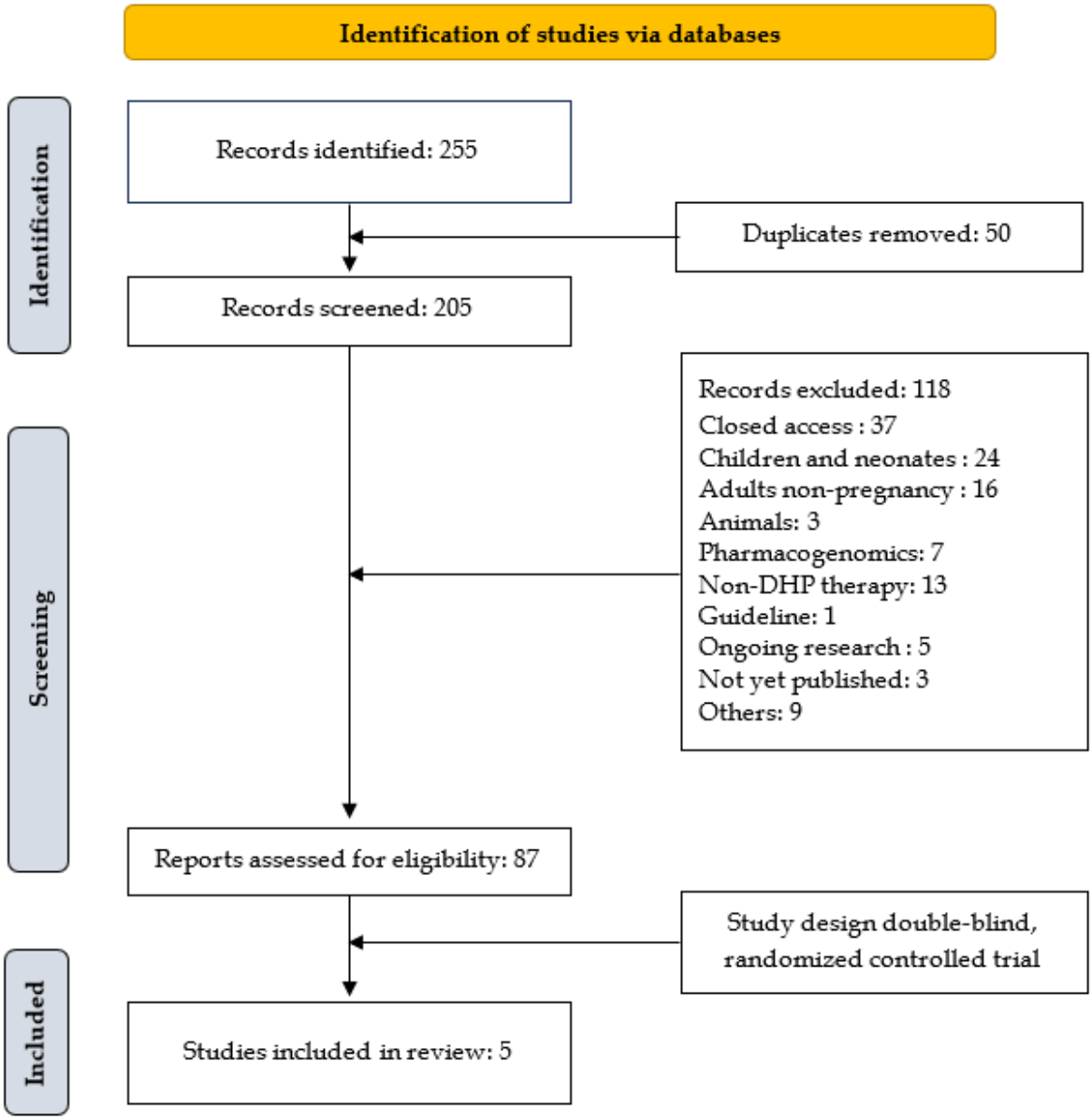

Figure 1. Flowchart of the article selection process

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A similar study conducted in 2018-2019 in Kenya, Malawi, and Tanzania compared the outcomes of Intermittent Preventive Treatment in pregnancy (IPTp) using DHP, SP, and DHP + Azithromycin (DHP+AZ). The findings indicated that pregnant women receiving IPTp DHP had a clinical malaria incidence of 29.1%, a malaria infection rate detected by microscopy during pregnancy of 34.5%, and a placental malaria incidence at delivery of 11.4%. In contrast, those using IPTp SP experienced a clinical malaria incidence of 48.2%, a malaria infection rate detected by microscopy during pregnancy of 70.8%, and a placental malaria incidence at delivery of 17.6%. The significant differences observed ($p<0.0001$) demonstrate that the use of DHP as IPTp is associated with a reduction in clinical malaria incidence, malaria infections detected by microscopy during pregnancy, and placental malaria incidence at delivery compared to the use of SP as IPTp.[27]

A recent study conducted in Busia, Uganda in 2024 demonstrated that monthly IPTp with DHP was more effective in reducing malaria-related fever incidents compared to IPTp with SP. According to this research, out of 334 pregnant women, only 3 experienced malaria-related fever after using IPTp DHP. In contrast, among pregnant women using IPTp SP, 71 out of 320 experienced malaria-related fever.[28]

Safety of *Dyhidroartemisin-Piperaquine* (DHP) Prolong the QTc Interval

The safety results can be seen in Table 2. Two studies were conducted in Busia, Uganda in 2022[29] and in Kenya, Malawi, and Tanzania in 2023.[27] These studies found that the use of IPTp DHP may cause QTc prolongation; however, the identified prolongation was mild and did not pose significant safety concerns. The QTc prolongation decreased as pregnancy advanced. In the first study, the change in QTcF (ΔQTcF) from the first to the last month decreased from a median of 19.6 to 17.1 milliseconds (ms), and similar to our study, QTc values before the second and third EKG doses were not significantly different from those before the initial dose. Overall, this data supports the conclusion that repeated DHP doses in healthy participants, including pregnant women, do not increase the risk of QTc prolongation.[29]

Table 1. Study Characteristics

Author, publication year	Setting	Sample size (n)	Intervention (n of patients)
[22]	Malawi	n= 1319	IPTp SP= 439 IPTp DHP+AZ=438 IPTp DHP+placebo=442
[24]	Maiduguri, Nigeria	n= 250	IPTp SP=125 IPTp DHP=125
[29]	Busia District, Uganda	n=748	IPTp SP=375 IPTp DHP=373
[28]	Busia, Uganda	n=654	IPTp SP=320 IPTp DHP=334
[27]	Kenya, Malawi, Tanzania	n=4680	IPTp SP= 1,561 IPTp DHP=1,561 IPTp DHP+AZ=1,558

IPTp = Intermittent preventive treatment in pregnancy; SP = sulfadoxine-pyrimethamine; DHP = dihydroartemisinin-piperaquine; AZ = Azithromycin

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Table 2. Studies Evaluating the Efficacy and Safety of DHP for Malaria Prevention in Pregnant Women

Reference	DHP Efficacy	DHP Safety on Pregnancy Outcomes
22	SP had a greater positive impact on pregnancy outcomes	SP reduced the risk of stillbirth compared to DHP and DHP+AZ
24	No significant higher incidence of placental malaria among groups DHP (63,1%) and SP (51,1%).	No stillbirth and congenital malformation reported among groups
29	no data available	DHP prolongs QT interval; however, as pregnancy progresses, the risk associated with QT prolongation decreases
28	SP = 26% reduction in malaria during pregnancy DHP was more effective in reducing clinical malaria during pregnancy. The reduction in placental malaria was higher for DHP than for SP.	SP has better outcomes for birth weight and provides protection against nonmalarial infections, particularly respiratory illnesses.
27	DHP 52% reduction in malaria during pregnancy and 34% reduction in placental malaria DHP+AZ 39% reduction in malaria during pregnancy and 15% reduction in placental malaria DHP and DHP+AZ were superior to SP in preventing malaria infections during pregnancy and at delivery.	Adverse pregnancy outcome (fetal loss, LBW, preterm birth, neonatal death) SP = 23,3% DHP = 27,9% DHP+AZ = 27,6%

3SP= 3dose SP, 3DHP = 3dose DHP, MDHP = monthly DHP

The degree of QTc interval prolongation observed with DHP depends on how it is administered. The smallest QTc prolongation occurred when the drug was administered on an empty stomach, while the greatest prolongation occurred after a high-fat/high-calorie meal.[30]

The second study, the addition of azithromycin resulted in a significantly longer QT prolongation compared to DHP alone (36 ms vs. 27 ms), with most women having QTc values exceeding 500 ms. The QTc prolongation progressively decreased with subsequent IPTp regimens, even in the dihydroartemisinin-piperaquine group that did not receive azithromycin.[27] Azithromycin can increase the QTc interval in hospitalized patients with community-acquired pneumonia (CAP), although this was not statistically significant.[31]

Adverse Pregnancy Outcome

Four studies indicated that unfavorable pregnancy outcomes were associated with the use of IPTp in pregnant women. These studies found that the incidence of adverse outcomes, such as preterm birth, low birth weight, and small-for-gestational-age infants, was higher in the group receiving IPTp DHP (27.9%) compared to IPTp SP (23.3%). Miscarriages

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were reported more frequently in the IPTp DHP group at a rate of 2.2%, while neonatal deaths were more common in the IPTp SP group at 1.3%.[27]

Based on previous research in 2022, the incidence of low birth weight occurred in 7.8% of infants in the IPTp SP group and 13.4% in the IPTp DHP group, while small-for-gestational-age infants were recorded at 16.3% in the SP group and 21.8% in the IPTp DHP group.[22] Placental malaria is associated with adverse outcomes such as preterm birth, low birth weight, stillbirth, and neonatal mortality.[32] IPTp-DHP can significantly reduce the incidence of low birth weight compared to IPTp-SP.[33]

Neonates born to mothers receiving IPTp-SP (16.2%) showed significantly better birth weights compared to those born to mothers receiving IPTp-DHP (21.3%). The risk of low birth weight was similar between the two groups, with a risk difference of 0.02% [28]. However, one study reported that the IPTp-SP group experienced a higher rate of adverse pregnancy outcomes, including spontaneous abortion (2.1%) and low birth weight (16%).[24]

Nausea and Vomiting

The subsequent analysis from a study involving 4,680 pregnant women in Kenya, Malawi, and Tanzania indicated that the most commonly reported side effects were nausea, vomiting, and dizziness, particularly within the first three days following medication administration. Among those receiving Dihydroartemisinin-Piperaquine (DHP), 3.4% experienced nausea, and 3.7% reported dizziness. In contrast, the incidence of these side effects was significantly lower in the Sulfadoxine-Pyrimethamine (SP) group, with only 0.3% of women reporting nausea or dizziness. Vomiting was also more frequently observed in the DHP group (0.3%) compared to the SP group (0.2%).[27] According to[34] DHP was associated with a higher risk of vomiting occurring approximately 30 minutes after medication administration; however, this was reported in a very small percentage of participants.

CONCLUSION

The use of DHP as IPTp is more effective in reducing malaria incidence compared to SP. However, IPTp with SP is considered safer than DHP due to the lower incidence of side effects. DHP may serve as an alternative IPTp option in cases where SP resistance is high. Nonetheless, more extensive data and clinical trials from various regions are necessary to further verify these conclusions.

Conflict of Interest

The authors declare no conflict of interest.

Authors' Declaration

The authors hereby declare that the work presented in this article is original and that any liability for claims relating to the content of this article will be borne by them.

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