



Influence of Intermittent Preventive Treatment with Sulphadoxine – Pyrimethamine (IPT-SP) on Neonatal Clinical Characteristics during Delivery at Owerri, South East, Nigeria

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ABSTRACT

Background: Malaria is a disease caused by a protozoan organism, the Plasmodium. The disease is endemic in the tropical areas of the world majorly, the Sub-Saharan Africa and to a lesser extent Asia. About 4 species of the Plasmodium (*falciparum*, *vivax*, *ovale* and *malariae*) which are transmitted by the female anopheles' mosquitoes essentially causes this disease in man. The disease has severe consequences especially on children, pregnant mothers and the elderly. The problems of malaria in pregnancy (MIP) are enormous, affecting both the mother (miscarriages, premature labour, and even maternal deaths etc) and her unborn baby (fetal abortions, preterm births, intrauterine growth restrictions (IUGR), small for date babies, poor APGAR scores at birth, increased admissions in the neonatal intensive care unit (NICU), low birth weights, even fetal losses and neonatal deaths etc). These innumerable consequences warranted the World Health Organization (WHO) to recommend and approve the use of Intermittent Preventive Treatment with Sulphadoxine Pyrimethamine (IPT-SP) for the prevention of Malaria in Pregnancy.

Aim: Primarily, we aimed to study some clinical characteristics of neonates born to mothers who received IPT-SP in their current pregnancies and to compare same with the non-IPT-SP born Neonates.

Methods: The main material for the study is Sulphadoxine Pyrimethamine that were administered longitudinally as Directly Observed Treatment (DOT) to 148 eligible mothers at varying gestational ages from the second trimester. These mothers were followed them up during their antenatal course to help collect as well as analyze their pregnancy outcomes including the clinical characteristics and then compare same with the outcomes of the other 148 recruited mothers who were not SP eligible. IPT-SP non eligible mothers have allergies to SP or were recruited while in labour. The conditions for eligibility were based on set inclusion and exclusion criteria. The pregnancy outcome of interest in this very study included the APGAR Scores at 1st minute, APGAR scores at 5th minute and Neonatal Birth weights.

Data Analysis: The results were subjected to statistical process in which data obtained was analyzed using the SPSS (Computer Software Package for Social Sciences) version 20.0 (SPSS, Inc, 2007, Chicago). The descriptive statistics (mean, standard deviation, percentages etc.) were arrived at for continuous variables. For the purpose of this study, any P-value less than ($<$) 0.05 was considered statistically significant at 95% confidence interval.

Results: The mean Apgar score at 1 minute was 8.0 ± 1.81 for the study group neonates and only 6.5 ± 2.41 for those in the control group. The average Apgar score at 5 minutes was 9.0 ± 1.71 for the study group neonates and only 8.0 ± 3.06 for the control. The study group neonatal mean Birth weight was $3.162 \text{ kg} \pm 0.53 \text{ kg}$, while $2.714 \text{ kg} \pm 0.94 \text{ kg}$ was for the control neonates.

Keywords: APGAR score, Birth weight, IPT-SP, Malaria in Pregnancy, Plasmodium.

INTRODUCTION

Malaria generally has remained a disease of global health importance with about 3.3 billion people in 97 countries at its risk and estimated 200 million cases annually. Leading about to 600,000 deaths yearly (WHO, 2015). It is caused by a protozoan organism, the Plasmodium. Six plasmodial species altogether present a significant health threat to humans. They include: *Plasmodium falciparum* which is usually considered the most important and deadly specie in terms of severity and deaths. Others are *P. vivax*, a major cause of illness across large parts of the world, and it is largely argued that deaths, due to this parasite have been underestimated (Niang et al., 2014). *P. ovale* (*P. ovale curtisi*, *P. ovale wallikeri*), and *P. malariae* which are much less common causes of significant disease. Just recently, the simian parasite *P. knowlesi* has emerged as a local but important cause of disease, including severe disease especially in Malaysia and other areas of Southeast Asia, where it is predominantly a zoonotic disease. Till date there is no definite evidence of primary human-to-human transmission of *P. knowlesi* (Ahmed and Cox-Singh, 2015).

It is worthy of note that Plasmodium knowlesi has been the sole cause of malaria in Malaysia from 2018 to

2022. The persistence of this zoonotic species has hampered Malaysia's progress towards achieving the malaria-free status awarded by the World Health Organization (WHO). Due to the zoonotic nature of *P. knowlesi* infections, it is important to study the prevalence of the parasite in the macaque host, the long-tailed macaque (*Macaca fascicularis*). Apart from *P. knowlesi*, the long-tailed macaque is also able to harbour *Plasmodium cynomolgi*, *Plasmodium inui*, *Plasmodium caotneyi* and *Plasmodium fieldi* (Shahari et al, 2024).

With rising cases of malaria and its complications especially in pregnancy, many countries in Sub-Saharan Africa introduced the WHO recommended IPT-SP into their national malaria control programs. This is to help prevent Malaria in pregnancy, MIP (Newman et al., 2006; Hill & Kazembe, 2006; East African Network for Monitoring Antimalaria Treatment, [EANMAT], 2003), but levels of coverage still remained a major issue in most countries. Although strenuous efforts were being made to increase coverage levels with IPT-SP, its effectiveness is also being threatened by increasing levels of resistance to SP across Africa (Campbell, Barauh, Narauin & Rogers, 2006; Allouche et al., 2004; Plowes et al., 2004; Ringwald, 2004; White, 2004). Yet unfortunately for IPT-SP, its effectiveness is also being threatened by increasing levels of resistance to SP across Africa (Chukwu et al, 2023). To help enforce the above, the World Health Organization (WHO) stipulated a guideline for the administration of IPT-SP. Part of the recommendations of this guideline include that: *"in areas of stable (moderate-to-high) malaria transmission, IPT with SP is recommended for all pregnant women at each scheduled antenatal care visit"*. In particular: it is recommended that the first IPT-SP dose should be administered as early as possible during the second trimester of gestation. Each SP dose should be given at least one (1) month from the other and can be given up to the time of delivery. The last dose of IPT with SP can be administered late (after 36 weeks) in the third trimester of gestation without safety concerns. (WHO Malaria Policy Advisory Committee Meeting 11-13 September 2012 Provided, WHO, Malaria in pregnant women 2017, Chukwu et al, 2023).

Malaria in pregnancy is said to be responsible for up to 800,000 infantile mortalities as well as a substantial number of miscarriages and very low birth weight (VLBW) neonates per year. These are all consequences of disease, malaria (WHO malaria guideline, 2006). 11% of maternal death is due to malaria (FIGO, 2010 [<https://www.figo.org/news/-maternal>]).

Equally, in areas of malaria endemicity, it is known that fetal abortions, premature labor, small-for-date babies, low APGAR score and low birth weight neonate and even fetal or maternal deaths are some of the consequences of malaria parasite invasion of the pregnant placenta. In the course of these invasions, cytokines and some inflammatory cells are released which also aid to further complicate the unfavorable pregnancy outcomes classically associated with malaria parasite sequestration in the placental intervillous spaces around the chondroitin sulphate, A (Falade et al, 2007; Williams, 1996). Most unfortunately, some of the neonates are born with poor APGA scores warranting an increase in the number of admissions into the Special Care Baby Units (SCBU).

Rationale for the Study: The continued menace of malaria in pregnancy (MIP) on fetuses and neonates have for long attained an unarguable major concern in Sub Saharan Africa and Asia. Thus, it is needful to study the effects of MIP on these newborns as well as ascertain the effects of IPT-SP on some Clinical Characteristics of neonates born to treated mothers and those of their untreated counterparts. Hence, we study.

Statement of Problem: According to the World Health Organization (WHO), Malaria in pregnancy (MIP) accounts for about 800,000 infantile mortalities with a large proportion of miscarriages and also very low birth weight (VLBW) babies per year (WHO malaria guideline, 2006). Studies has equally demonstrated that some inflammatory cells and cytokines that are characteristic of malaria disease in pregnancy (MIP) can invade the placental bed leading to a wholesome derangement of foetal blood and other nutrient supplies. In its consequence, the foetus may be born having a low weight at birth or even small-for date. Some neonates may even suffer from prematurity with all its attendant sequelae. Small-for date neonates are at high risks of neonatal or infantile morbidity and mortalities (Falade et al, 2007; van Geetruyden, Thomas, Erhart & D' Alessandro, 2004). The problems of malaria in pregnancy (MIP) are innumerable warranting even more studies tailored towards preventing the condition from arising and hence, we chose to study.



MATERIALS & METHODS

Study Setting

This prospective cohort study was conducted among pregnant women attending antenatal care at the Federal Medical Centre (FMC), Owerri, Nigeria.

The study was carried out between June 2015 and December, 2016 (18 months). Prior to the commencement of bench work, the study protocol was approved by the FMC's Ethics Committee. Before participating in the study, all enrolled women volunteered a written informed consent. This was done after adequate counselling.

Inclusion Criteria

The inclusion criteria only allowed pregnant women who did consent to the study as well as satisfied all inclusion criteria to be recruited for the study. Included in the study were women who were ready to take IPT-SP before the principal investigator or the assistants as directly observed treatment short course (DOTS) for the study group only. Also, women residing in Owerri or its suburbs to assist them afford ANC follow up and readiness to deliver at FMC, Owerri (these was for both the study and control groups. Women ancillary body temperature of $< 37.5^{\circ}\text{C}$ and without any symptoms nor signs of malaria disease and no laboratory diagnosis of malaria (for both the study and control groups). Such women should not have ingested any antimalaria drug at least ≥ 2 weeks (for both the study and control groups).

The inclusion criteria for the control group included pregnant women that presented in labour (unbooked cases) or those that came for booking in the last months of pregnancy (late booking) as well as those with allergies to SP. Those that have allergies to SP were termed SP not eligible. All these women must meet all other criteria for inclusion before consideration for recruitment. At FMC Owerri, IPT-SP protocol parturients receive only 2 doses of IPT-SP (3 doses for HIV/AIDS and SCD patients). Also, parturients were not given SP in the last month of pregnancy at the time of this study. So recruited participants in the Study group received only 2 doses of IPT-SP

Exclusion Criteria

Some pregnant women with confounding factors were also excluded from the study. They included women with symptoms and signs of severe malaria, women with underlying medical or other diseases (known hypertensive, diabetics, other co morbidities), non-consenting women etc.

Study Protocol

All women who met the inclusion criteria during the study period were invited to participate. All the pregnant women in the study group (case) received 2 doses of the IPT-SP preferably at the first and second antenatal visits after 'quickening'. Those in the control arm did not receive any SP. Where necessary, the study also involved home visitations to facilitate follow-up. While the two doses of SP were given at least 1 month apart, the IPT-SP was administered as directly observed therapy (DOT). Sometimes the SP was administered on an empty stomach where necessary. The IPT-SP was administered at a stat dose of three (3) tablets with each tablet containing 500mg/25mg SP, giving the total required dosage of 1500mg/75mg of SP per study group participant. No IPT-SP drug was given to the Control group women.

All the drugs (IPT-SP) administered to these pregnant women were **PROCURED** by the principal researcher and given to the selected pregnant women **FREE**. This was to ensure that the right drugs and dosages were used for the study as well as maximize compliance.

The instrument of this study was a well-structured Questionnaire. A total of 30 well – framed questions were applied to each subject in both groups based on the set objectives. We chose to **administer the questionnaires** since we had both literate and illiterate participants. A total of 200 questionnaires were administered to about 200 parturients in each group (total of 400 questionnaires), expecting to get the calculated 148 parturients from



each group at the end. Those that failed to complete the study accounted for the extra 52 questionnaires in each group.

Follow Up

At each visit following booking and recruitment, adequate interval history was taken and physical examination done. The aim was to ascertain the state of health of the participant during the period from the last visit. Routine antenatal investigations done included Haemoglobin estimation and Urinalysis. Malaria Parasite and other tests were done for suspected cases. Those that tested positive to malaria were treated, discarded from the study as well as replaced. Other conditions that could affect the result outcome were equally treated accordingly. This was to reduce the influence of such illnesses on the study outcome. Also, any attrition was replaced to ensure that the sample size of 148 pregnant women per group was attained. The follow-up exercise continued till delivery to enable data to be collected. APGAR Score at birth, 1 & 5 minutes and birth weights of the neonates were duly recorded as well as analysis subsequently. Follow-up procedures included home visits, phone calls and even direct contacts with their spouses.

Data Analysis

The results gotten from this study were subjected to analysis using the “One-way Analysis of Variance” (ANOVA) using the Computer Software Package for Social Science (SPSS) version 20.0 (SPSS, Inc, 2007, Chicago) and then presented as Mean $\pm$ Standard Deviation. The means of all the study and the control group findings were compared to ascertain the value of IPT-SP in the prevention of malaria in pregnancy as regards neonatal clinical characteristics. All values of $p = < 0.05$ were considered statistically significant.

Table 1.0: Shows the summary clinical characteristics for the Neonates studied. The mean one (1) minute Apgar score of the neonates was 8 ± 1.81 for the study group and 6.47 ± 2.41 for the control group. The average 5-minute Apgar score for the neonates was 9 ± 1.71 for the study group and 8 ± 3.06 for the control group. In that same table, the average Birth weight of the neonates was $3.162 \text{ kg} \pm 0.53 \text{ kg}$ for the study (treatment) group and $2.714 \text{ kg} \pm 0.94 \text{ kg}$ for the control group. See table 1.0 below.

DISCUSSION

This study which assessed the influence of Intermittent Preventive Treatment with Sulphadoxine – Pyrimethamine (IPT-SP) on Neonatal Clinical Characteristics made very valuable research findings. The study found that neonates born to mother who received intermittent preventive treatment with Sulphadoxine-Pyrimethamine (IPT-SP) had better birth weights (minimum of 1.1 – maximum of 4.6 kg) with a mean birth weight of $3.162 \text{ kg} \pm 0.53 \text{ kg}$. On the other hand, the neonates born to mothers who did not receive intermittent preventive treatment with Sulphadoxine-Pyrimethamine (IPT-SP) had lower birth weights (minimum of 0.9 – maximum of 4.6 kg) with a mean birth weight of $2.714 \text{ kg} \pm 0.94 \text{ kg}$.

The IPT-SP group recorded fewer cases of low birth weight (LBW) and also fewer very low birth weight neonates (VLBW). It can also be noted that our report does not entirely agree with the findings by Olukemi and co where the p-value for having LBW between the cases and control was statistically significant, $p \text{ value} = 0.016$. Comparing neonates whose mothers had IPT-SP with those whose mothers did not, mean birth weight was $3.13 \text{ kg} \pm 0.52$ versus $3.0 \text{ kg} \pm 0.56$, $p = 0.016$ (Olukemi, Adebola & Olusegun, 2011).

In the further assessment of the neonatal clinical characteristics, the Apgar score was noted to be equally better in both the 1st and 5th minutes after birth among the study group neonates (8.0 ± 1.81 & 9.0 ± 1.71 respectively) than the control (6.5 ± 2.41 & 8.0 ± 3.06 respectively). These findings underscore the importance of IPT-SP in the prevention of malaria in pregnancy and also compared to the finding with those from a study at Uyo, Nigeria where Ibanga and co reported that at 5 minutes, 3.3% of their parturients had an Apgar score of ≤ 6 while 96.3% had a score of ≥ 7 (Ibanga et al, 2015). The Ibanga an co study also reported that, Placental malaria predisposed to low birth weight (OR 1.01{95%CI 1.001 – 1.02}, $p = 0.04$) and fetal anaemia (OR 1.02{95%CI 1.01 – 1.03}, $p < 0.001$). These findings also agreed with the results of this resent study where the parturients in the study group had neonates with better birth weights. Olukemi and colleagues, documented



that IPT-SP use was associated with a mean birth weight of 3.13 kg $\pm$ 0.52 versus 3.0 kg $\pm$ 0.56 ($p = 0.016$) while non-use was associated with increased risk of having low birth weight babies (AOR: 2.27, 95% CI: 0.98; 5.28). In that study, the overall low birth (LBW) was 19.4% (Olukemi, Adebola & Olusegun, 2011).

The 1-minute Apgar score of this study agreed with the results of another study in which the mean APGAR score at 1 minute, was ($\pm$ S.D.) 8.9 [1.2]. In that same study, the mean Apgar score at 10 minutes was ($\pm$ S.D.) 9.8 [0.97] (Daud et al, 2014). In another Nigerian study, the neonates of the participating mothers had a mean Apgar score of 8.00 $\pm$ 0.99 (compare: 8.0 $\pm$ 1.81, from our study) in the 1st minute. The mean Apgar score in the 1st minute for neonates of women who received SP was 8.01 $\pm$ 0.92 in comparison to those that received proguanil with a mean Apgar score of 7.99 $\pm$ 1.07 in the 1st minute, $P=0.971$ (Jeremiah, Kasso & John, 2012). Both findings compared favourably with the results of this very study.

Again, the importance of antenatal IPT-SP can no longer be over emphasized since the benefits on the neonatal clinical characteristics are very evident in these research findings that are being reported. This goes further to reaffirm earlier research findings. It can also be noted that our report does not entirely agree with the findings by Olukemi and co where the p -value for having LBW between the cases and control was statistically significant, $p = 0.016$. Comparing neonates whose mothers had IPT-SP with those whose mothers did not, the mean birth weight was 3.13 kg $\pm$ 0.52 versus 3.0 kg $\pm$ 0.56, $p = 0.016$ (Olukemi et al. 2011). Ibanga and co concluded from their study that, Placental malaria was associated with adverse pregnancy outcomes such as low birth weight, fetal anaemia and cord parasitaemia and their findings compared to ours where 5.2% of their neonates were of LBW, and 94.8% of normal birth weights (Ibanga et al., 2015).

RECOMMENDATIONS

From the findings of this study, to ensure better neonatal characteristics from birth, the coverage and implementation of IPT-SP should be taken seriously while efforts should be made to ensure that all pregnant women books for ANC early as well as receives at least 2 doses of the recommended IPT-SP before delivery.

CONFLICT OF INTERESTS

It should be noted that as far as this study is concerned, the authors hereby declare that there was no conflict of interest.

Table 1.0: Summary Neonatal Clinical Characteristics Studied (Children)

	Study Group					Control				
Measure	N	min	Max	mean	Std. dev	n	Min	Max	Mean	Std. Dev
Birth weight (Kg)	148	1.1	4.6	3.162	0.534	147	0.9	4.6	2.714	0.935
1 minute Apgar score	148	0	10	8	1.807	148	0	9	6.473	2.414
5 minutes Apgar score	148	0	10	9	1.712	148	0	10	7.986	3.055

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