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# The Influence of Magnesium Sulphate Fortified Haematinics on the Prevention of Preeclampsia and Anaemia In Pregnancy In Ibadan

Olayinka Oladunjoye Ogunbode, Ayodele Olatunji Arowojolu,  
Christopher Odianosen Aimakhu, Folasade Adenike Bello

*Department of Obstetrics and Gynaecology, College of Medicine, University of Ibadan*

## ABSTRACT

**Background:** Hypertensive disorders of pregnancy and anemia in pregnancy are common direct and indirect causes of maternal deaths and morbidities, and the need for routine haematinics supplementation in Sub-Saharan Africa is well documented. Magnesium Sulphate has been proven to be of benefit in the treatment of preeclampsia and eclampsia. **Aim:** To determine whether haematinics fortified with magnesium sulphate (Jawaron® soft gel capsules) helps in reducing the incidence and complications from preeclampsia while also assessing its effectiveness in preventing anaemia in pregnancy and attendant complications. **Settings and Design:** The study was prospective and interventional involving four hundred and ten (410) pregnant women recruited before 20 weeks' gestation. **Methods and Materials:** The participants were randomly allocated into two groups, the first group received MgSO<sub>4</sub> fortified haematinics while the second group had routine haematinics (5mg Folic acid and 200mg Ferrous sulphate) and both groups were followed up till delivery. **Results:** There was a slight reduction in the mean systolic blood pressure (112.2mmHg ± 14.0 to 111.3mmHg ± 13.9) at delivery among the MgSO<sub>4</sub> fortified haematinics group. None of the patients in the two groups developed preeclampsia however 17 (4.3%) participants developed pregnancy induced hypertension. The prevalence of anaemia in labour and shortly before delivery among the MgSO<sub>4</sub> fortified haematinics and those on routine haematinics was 7.0% and 9.5% respectively, without any statistically significant difference. **Conclusion:** The prevalence of preeclampsia and anaemia in this study was similar amongst pregnant women in the two groups, although with better systolic blood pressure at delivery in the MgSO<sub>4</sub> fortified haematinics group. It is recommended that the single dosage combined haematinics formulations should be used in ante-natal care clinics where better compliance with therapy is desired.

**Keywords:** Preeclampsia, Anaemia, Magnesium Sulphate, Haematinics

## Corresponding Author

Dr. Olayinka O. Ogunbode  
Dept of Obstetrics & Gynaecology,  
College of Medicine, Uni. of Ibadan  
yinkaogunbode@yahoo.co.uk  
+234 802 3258010

## Introduction

Hypertensive disorders in pregnancy are one of the major causes of maternal mortality globally.<sup>1</sup> It is more common in sub-Saharan Africa accounting for about 20-29% of all maternal mortalities.<sup>1,2</sup> About 15% of all cases of hypertension in pregnancy results in preeclampsia/eclampsia and with case fatality rates of 14.7% to 46.4%.<sup>2-4</sup> The aetiology of preeclampsia remains unknown despite various theories, and some of which include vascular endothelial injury, maternal-paternal immune mal-adaptation, complete or partial failure of trophoblastic invasion, altered vascular reactivity, decreased intravascular volume, imbalance between prostacyclin and thromboxane, nulliparity, diet and genetics.<sup>1,5,6</sup>

Anaemia in pregnancy is a global public health problem, although more common in developing countries.<sup>7</sup> It also has implications on both social and economic development. The World Health Organization (W.H.O.) estimates the prevalence rates of anaemia in pregnant women to be in the range of 40-60% in developing countries but some Nigerian studies have found rates as high as 80%.<sup>8,9,10</sup> This is a far cry from the 14% estimates in developed countries. The W.H.O. cut off for anemia in pregnancy is Hb <11.0g/dl and based on the haemoglobin concentration in g/dl is categorized as mild, moderate and severe (9.0-10.9, 7.0- 8.9 & <7.0) respectively.<sup>11</sup> Nutritional anaemias are by far the most common among pregnant women.<sup>11</sup> The prevalence and severity of anemia depends on gravidity, malaria endemic regions, bone marrow diseases, Human immunodeficiency virus (HIV) infection, viral and bacterial infections amongst other factors.<sup>12</sup> Anaemia has major health risks to the mother and fetus, with 20% of maternal deaths attributed directly or indirectly to it and leading to post-partum haemorrhage, preterm births, intrauterine growth restriction, low birth weight infants and increased perinatal morbidity and early infant deaths.<sup>12</sup>

Interventions in antenatal care that can help to reduce the burden of anemia in pregnancy include health education, early detection through screening, prevention of malaria through inter-

mittent presumptive therapy, the use of insecticide treated nets and the administration of haematinics.<sup>13</sup> In developing countries, the use of haematinics in pregnancy had been attributed to the decline in the complications from anaemia in pregnancy and recently these haematinics come fortified with various other trace elements and vitamins, one of which is magnesium in the formulation of Magnesium sulphate.<sup>14,15</sup>

Magnesium plays a vital role in metabolic processes, blood pressure regulation and neuromuscular excitability and its deficiency in pregnancy results into maternal and fetal outcomes, such as intrauterine growth restriction, sudden infant death syndrome, uterine hyperexcitability, premature labour and preeclampsia.<sup>16</sup> Low magnesium levels in pregnant women is commonly associated with increased consumption by the growing fetus, haemodilution and increased renal clearance. During normal pregnancy, levels of ionized and total magnesium decreases as gestational age increases.<sup>16</sup> The use of antenatal magnesium sulphate (MgSO<sub>4</sub>) fortified haematinics has been recommended for fetal neuro protection<sup>17</sup> however, its potential benefit in the prevalence, severity and complications of preeclampsia/eclampsia complex has not been evaluated.

This study aimed to determine the influence of oral haematinics fortified with supplemental Magnesium Sulphate, using Jawaron<sup>®</sup> soft gel capsules, during pregnancy on the incidence of anaemia in pregnancy and preeclampsia and other benefits.

## Materials and Methods

The study was carried out among pregnant women presenting for booking before 20 weeks of gestation at the booking at the Ante-natal Clinic of the University College Hospital, Ibadan Nigeria and the study design was an interventional longitudinal prospective type. Ethical approval was obtained from the University of Ibadan/ University College Hospital, Ibadan Institution Research Board. Consecutive sampling technique was used. Women with hypertension at booking, known patient with

epilepsy and prior history of preeclampsia or hypertension in pregnancy were excluded. Following informed consent, they were randomly allocated to into either of the two study groups through a computer-generated table. The minimum sample size was calculated using the formulae for cohort studies and 368 was obtained. This was approximated to 406 participants after adding a 10% attrition rate.

The survey was self-administered and face-validated by colleagues, then pre-tested on non-participant pregnant women from the Catholic Hospital, Oluyoro Oke-Offa, Ibadan and were completed at enrolment. After randomization, the first group had Jawaron® soft gel capsules (NAFDAC No. A4-3667), one tablet daily, with each tablet containing 2mg of Folic acid, 150mg of ferrous fumarate, and 60.0mg of magnesium sulphate BP while the second group had folic acid 5mg and ferrous sulphate 200mg (60mg elemental) tablets daily. Stocks of medications were given monthly. The data on blood pressure measurements, urinalysis, packed cell volume and other secondary outcomes were updated at subsequent visits until delivery.

The blood pressure was calculated as the average of two measurements carried out after fifteen minutes' rest and at five minutes intervals in the sitting position using a standard mercury sphygmomanometer and an appropriate sized cuff. Hypertension was defined as systolic blood pressure of 140mmHg and above and or diastolic blood pressure of 90mmHg and above. Gestational age was assessed by the history of the last menstrual period and an ultrasound report within the first 12 weeks of pregnancy. The urine sample was tested for protein using Multistix reagent strips (Bayer Diagnostic Division, Saxonburg, USA). The Packed Cell Volume (PCV) was estimated using Mission Hb. Haemoglobin Testing system (ACON Laboratories Inc., San Diego, U.S.A.). The study was strictly confidential, and participants had the freedom to refuse to fill the questionnaire or withdraw from the study at any point in the study.

## Results

A total of 406 participants were recruited for this study but only 400 completed the study. The mean age of the participants was 31.38 ± 4.6 years. Most (72.7%) of the participants were in the age group 26-35 years. The predominant religion was Christianity (316; 79%) while 83(20.7%) were of the Islamic faith. Three hundred and thirty-seven (84.2%) were Yorubas distantly followed by the Igbos (54;13.5%). Most (97.7%) of the participants had at least the secondary school form of education, out of which the tertiary education accounted for 80.7%. The predominant occupational class of the respondents was skilled workers. Only 37 (9.2%) participants were professionals. This is shown in Table 1.

Table 2 shows the obstetrics parameters of the respondents. The highest number of participants (201; 50.3%) were pregnant women with one and two parous experiences, closely followed by those with no previous parous experience (172, 43.0%). Nearly all the participants (396; 99.0%) had no previous history of elevated blood pressure. None of the participants had a history of previous convulsive episode. Only seven participants (1.3%) had a positive family history of hypertension.

The prevalence of anaemia at recruitment was 6.5% and 36.3% using a PCV <30% and PCV <33% respectively as the definition of anaemia. There was a slight improvement in the PCV just before delivery amongst the routine haematinics group compared to the Jawaron® soft gel capsule as shown in Table 3. However, this finding was not statistically significant. Similarly, about the same percentage of participants developed pregnancy-induced-hypertension in the two groups. There was a slight drop in the mean systolic pressures at delivery in the Jawaron® soft gel capsule group, however this finding was also not statistically significant. This is shown in Table 3.

The relationship between the medications taken and the outcome of labour is shown in table 4. Vaginal delivery (145; 36.5%) was highest in the Jawaron® soft gel capsule group. Those in the

routine haematinics group had more live births (196; 49.1%) while an equal number of participants (5; 1.2%) had still birth infants. Two participants had miscarriages in the Jawaron® soft gel group while none in the routine haematinics had a miscarriage. An equal number of participants (171; 42.8%) from the two groups delivered

fetuses with the birth weight 2.5kg to 4.0kg. More of the babies in the folic acid and ferrous sulphate group (187; 96.2%) had normal APGAR scores at 1 minute and similarly two hundred participants (50%) had normal APGAR scores at 5 minutes. These differences were not statistically significant.

**Table 1. Socio-demographic characteristics of the study participants**

Category	Jawaron® soft gel capsules No. (%)	Folic acid and Ferrous sulphate No. (%)	Total No (%)	P-Value
Mean age(yrs)	31.5 + 4.8	31.3 + 4.3	31.4 + 4.6	
<b>Age group (yrs)</b>				
<21	3(1.6)	2 (1.0)	5 (1.3)	0.87
21- 25	12(6.3)	11 (5.5)	23 (5.7)	
26 -30	75 (39.3)	80 (39.8)	155 (38.7)	
31-35	69 (36.1)	75 (37.3)	144 (36.0)	
36-40	34 (17.8)	30 (14.9)	64 (16.0)	
>40	6 (3.1)	3(1.5)	9 (2.3)	
<b>Religion</b>				
Christianity	156 (78.4)	160 (79.6)	316 (79.0)	0.59
Islam	42 (21.1)	41 (20.4)	83 (20.7)	
Others	1 (0.5)	0 (0.0)	1 (0.3)	
<b>Tribe</b>				
Yoruba	169 (84.9)	168 (83.6)	337 (84.2)	0.41
Igbo	28 (14.1)	26 (12.9)	54 (13.5)	
Hausa	1 (0.5)	3 (1.5)	4 (1.0)	
Others	1 (0.5)	4 (2.0)	5 (1.3)	
<b>Educational Level</b>				
None	1 (0.5)	2 (1.0)	3 (0.8)	0.21
Arabic	0 (0.0)	5 (2.5)	5 (1.2)	
Primary	0 (0.0)	1 (0.5)	1 (0.3)	
Secondary	23 (11.6)	21 (10.5)	44 (11.0)	
Tertiary	165 (82.9)	158 (78.6)	323 (80.7)	
Post-Tertiary	10 (5.0)	14 (7.0)	24 (6.0)	
<b>Occupation</b>				
Unemployed	21 (10.6)	24 (11.9)	45 (11.2)	0.95
Unskilled	3 (1.5)	4 (2.0)	7 (1.8)	
Semi-skilled	62 (31.2)	62 (30.9)	124(31.0)	
Skilled	96 (48.2)	91 (45.3)	187 (46.8)	
Professional	17 (8.5)	20 (10.0)	37 (9.2)	
<b>Total</b>	199(100.0)	201(100.0)	400(100.0)	

**Table 2. Obstetrics parameters of the study participants**

Category	Jawaron® soft gel capsules No. (%)	Folic acid and Ferrous sulphate No. (%)	Total No (%)	P-Value
<b>Parity</b>				
0	82 (41.2)	90 (44.8)	172 (43.0)	0.52
1-2	103 (51.8)	98 (48.8)	201(50.3)	
2-4	14 (7.0)	9 (4.5)	23(5.7)	
>4	1(0.5)	3(1.5)	4 (1.0)	
<b>History of elevated blood pressure</b>				
Present	0 (0.0)	4 (2.0)	4 (1.0)	0.06
None	199 (100.0)	197 (98.0)	396 (99.0)	
<b>History of convulsion</b>				
Present	0 (0.0)	0 (0.0)	0 (0.0)	0.00
None	199(100.0)	201 (100.0)	400 (100.0)	
<b>Family history of Hypertension</b>				
Present	3 (1.5)	4 (2.0)	7 (1.7)	0.5
None	196 (98.5)	197 (98.0)	393 (98.3)	
<b>Total</b>	<b>199(100.0)</b>	<b>201(100.0)</b>	<b>400(100.0)</b>	

**Table 3. Associations between the prevalence of anaemia and hypertension at booking and at delivery among the participants**

Category	Jawaron® soft gel capsules No. (%)	Folic acid and Ferrous sulphate No. (%)	Chi- square	P-Value
<b>PCV at booking</b>				
<30	13(6.5)	13(6.5)	0.02	0.56
>30	186(93.5)	188(93.5)		
<b>PCV at booking</b>				
<33	73(36.7)	72(35.8)	0.05	0.46
> =33	126(63.3)	129(64.20)		
<b>PCV during delivery</b>				
<30	14(7.0)	19(9.5)	1.12	0.19
>30	185(93.0)	182(90.5)		
<b>PCV during delivery</b>				
<33	63(31.7)	59(29.4)	0.29	0.33
> =33	136(68.3)	142(70.6)		
<b>Blood Pressure at delivery</b>				
Normotensive	191(96.0)	192 (95.5)	0.059	0.508
Hypertensive	8(4.0)	9 (4.5)		

Category	Jawaron® soft gel capsules No. (%)	Folic acid and Ferrous sulphate No. (%)	Chi- square	P-Value
<b>PCV at Booking</b>				
Mean	33.5 + 3.0	33.5 + 3.6	-0.09	0.93
Range	21 - 41	24 - 42		
<b>PCV during delivery</b>				
Mean	34.1 + 3.1	34.2 + 3.2	-0.03	0.98
Range	24 - 45	21 - 40		
<b>Blood Pressure at booking</b>				
Mean Systolic	112.2 ± 14.0	110.3 ± 14.4	1.22	0.22
Mean Diastolic	69.0 + 10.1	68.2 + 8.9	0.91	0.36
<b>Blood Pressure at delivery</b>				
Mean Systolic	111.3 ± 13.9	112.2 ± 14.81	-0.61	0.6
Mean Diastolic	70.3±11.8	68.8±11.8	1.30	0.2

## Discussion

Most of the participants in this study with MgSO<sub>4</sub> fortified haematinics versus routine haematinics were from the ages 25-34 years which form the peak ages of fertility for women in the reproductive age. This finding is similar to other studies conducted in tertiary hospitals in Nigeria.<sup>18,19</sup> This research was conducted in the south-western parts of Nigeria where more emphasis is placed on education of the female child, thereby more likely to delay the age of marriage and childbearing. In areas where early marriages are practiced, either for cultural or religious beliefs, the younger age groups form a greater proportion of women attending ante-natal clinics.<sup>20</sup> The religion, tribe and educational status also conforms with the socio-demographic characteristics of the south-west region of Nigeria.

In this study, with the Jawaron® soft gel group versus routine haematinics group, using the cutoff of haemoglobin concentration of lower than 10g/dl recommended by Lawson et al., the prevalence of anemia at booking from this study was 6.5% compared to rates as high as 54.5% - 64.1% observed in South-East Nigeria and North-East Africa.<sup>18,19,21,22</sup> This lower cut-off is commonly used because most parturients with slightly lower levels do not suffer any debility due to the

chronicity of low haemoglobin levels.<sup>23</sup> On the other hand, the prevalence of anaemia was much higher (36.3%) using the W.H.O recommended cut-off of a haemoglobin concentration of less than 11g/dl.<sup>11</sup>

It is well known that pregnant women in the tropics require routine haematinic supplementation and the W.H.O. recommendation of 5ug of Folic acid and 60mg of elemental iron daily for developing countries is commonly accepted as the benchmark.<sup>11</sup> Of recent, because of the poor compliance associated with the use of routine haematinics, combination products are being preferred. In this study to explore the benefit of MgSO<sub>4</sub> fortified haematinics as against routine haematinics, the prevalence of anemia remained relatively unchanged using the lower cut-off but increased just before delivery using the W.H.O. cut-off. This brings into limelight the issue of compliance, as a much higher improvement in the haemoglobin levels would have been expected, and the likelihood that many women pregnant women did not take their medications regularly, as well as the contribution of physiological anaemia in the diagnosis of anemia before delivery.

There was not much difference in the improvement in the haemoglobin concentration in the two groups, however a potential benefit of

Jawaron® soft gel capsule over the routine folic acid and ferrous sulphate supplementation is the ease of administration of the drugs. It is taken only once daily compared with the multiple dosing with the routine hematinics. This has the potential for increased compliance as fewer gastrointestinal effects are expected from a capsule, than from a tablet. A study on the compliance with medications has found that the rates are best with directly observed therapies but better with single compared to multiple doses. The influence of Jawaron® fortified soft gel capsule compared to the routine hematinics on the development of preeclampsia was however not established in this study.

There was a mild improvement in the systolic blood pressure in the Jawaron® soft gel capsule at delivery, but this finding was not statistically significant. The advantage of MgSO<sub>4</sub> fortified haematinics in antenatal care is documented to include fetal neuro protection.<sup>17</sup> Magnesium helps in control of blood pressure and neuromuscular activities with low levels leading to intrauterine growth restriction, sudden infant death syndrome, uterine hyperexcitability, premature labour and preeclampsia.<sup>16</sup> None of the participants in the study developed preeclampsia while a few developed pregnancy induced hypertension. Similar proportions of patients in the two groups developed pregnancy-induced-hypertension and this was not statistically significant.

From this study, there were no adverse effects of either groups on fetal outcomes. More of the babies were appropriate for gestation but those on routine haematinics had more macrosomic babies, although this was not statistically significant. This finding of macrosomia is not expected and was surprising as compliance should likely have been poor amongst the routine haematinics group due to financial constraints in developing countries.

This should have affected the birth weights with more smaller babies expected. On the other hand, could it be that the diet among pregnant women may have improved with improving health education and health talks compared to the past and this may have compensated for the deficits associated with poor drug compliance. The prevalence of birth asphyxia was low and similar in the two groups and this observation was not statistically significant. Almost all the babies had good 5 minutes APGAR scores, and these must have been because of the prompt resuscitative efforts.

In conclusion, this study has shown some benefit of the MgSO<sub>4</sub> fortified haematinics-Jawaron® fortified soft gel capsules, on the blood pressure of pregnant women compared with routine haematinics alone and this may help to reduce the morbidities and mortalities associated with preeclampsia and anemia among the pregnant population, however, larger multicenter studies may be needed to confirm this finding. It also revealed the need to further evaluate the issue of compliance of pregnant women with medications in this environment as the improvement in anaemia in pregnancy observed in this study was less, however the easy-to-use MgSO<sub>4</sub> fortified haematinics-Jawaron® fortified soft gel capsule will be advantageous for pregnant women in this environment.

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#### **Conflict Of Interest**

There was no conflict of interest.

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