

Effect of Moringa Oleifera Plus Royal Jelly Capsules in The Gestation Age and Placenta Weight of Newborns in Indonesia

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ABSTRACT

Background: The incidence of adverse birth outcomes (ABO) in low- and middle-income countries (LMIC) remains significantly elevated. Moringa oleifera (MO), rich nutritional profile, offers to reduce ABO. Therefore, this study aimed to evaluate the impact of MO plus royal jelly capsules on the gestational age and placental weight of newborns in Indonesia. **Materials and Methods:** A quasi-experimental design setup in the Banggai district, Central Sulawesi Province. The study used a purposive sampling of 80 pregnant women from each sub-district. Moilong District received MRJ, while South Batui District was the Multiple Micronutrient Supplement (MMS) control group. Both groups took one capsule daily for six months. Data analysis using SPSS v28 for Windows, including Chi-square/Fisher's exact test, Kolmogorov-Smirnov test, Mann-Whitney test, and ANCOVA, with a significance level of $p < 0.05$. **Results:** The demographic characteristics in both groups were similar ($p > 0.05$), except for BMI ($p=0.031$). Pregnancy outcomes data were also identical ($p > 0.05$). The Mann-Whitney test did not show a significant difference ($p = 0.696$) in the gestational age of delivery between the groups. However, there was a significant difference ($p < 0.05$) in the PW variable within the MRJ group, as shown by the Mann-Whitney test. After adjusting for BMI in PW, the ANCOVA test indicated a significant difference ($p = 0.001$). **Conclusions:** The study concludes that MRJ and MMS interventions are effective and safe in preventing ABO in newborns based on gestational age and placental weight.

Keywords: Adverse Birth Outcomes, Multiple Micronutrient Supplement, Moringa Oleifera, Pregnancy outcomes, Pregnant Women.

INTRODUCTION

Adverse birth outcomes (ABOs), including pre-term birth (PTB), low birth weight (LBW), macrosomia, congenital anomalies, and stillbirth, are impacted by multiple factors.¹ PTB is defined as delivery <37 weeks of gestation age, while LBW refers to newborns weighing <2500g² These outcomes negatively impact infant health and pose economic challenges in low- and middle-income countries (LMICs), especially in places like Indonesia.^{3,4} The 2023 Indonesian Health Statistics Profile showed an increase in child mortality, with 34,226 children under five dying, 80.4% (27,530 deaths) of which were neonates, marking a rise from the reported in 2022.^{5,6}

A balanced diet during pregnancy is essential to match the placenta's nutrient supply with the fetus's growth demands; imbalance can cause issues like fetal growth restriction or macrosomia (newborns weighing >4000g).⁷⁻⁹ Additionally, macrosomia, which can occur in post-term pregnancies (delivery >42 weeks), elevates the risk of complications like fetal malnutrition, increased cesarean delivery rates, and stillbirth.^{9,10} The placenta plays a significant role in delivering nutrients, and its overall health and size are significant factors in fetal development.^{11,12} Placental weight (PW) typically ranges from 300g to 890g, averaging 590 ± 82 g.¹³ Research has shown that a lower PW is associated with chronic hypertension/preeclampsia, while a higher PW is associated with maternal anemia, gestational diabetes, and ABO incompatibility.^{14,15}

Moreover, the complex interplay of malnutrition during gestation is significantly associated with an increased risk of ABO, primarily due to a lack of adequate consumption of vital macro- and micronutrients.¹⁶

Essential micronutrients, including vitamins and minerals, are crucial for the embryo's healthy development, fetal and maternal health, highlighting the importance of increased nutritional intake during pregnancy.^{17,18} Maternal nutritional deficiencies can negatively affect fetal development and lead to ABO, with common deficiencies including iron, folate, vitamins B12 and D, iodine, and zinc.¹⁹ The inadequate intake of these micronutrients can impair fetal development.²⁰ Therefore, nutritional supplements are recommended, especially for those avoiding certain food groups or at higher risk of deficiencies, as a cost-effective strategy to minimize ABO risks.^{21,22}

Moringa oleifera (MO) is a nutrient-rich plant that can be used as a non-pharmacological supplement to address malnutrition, especially in LMICs.²³⁻²⁶ MO dried leaves are beneficial during pregnancy and lactation due to their high content of iron (97.9 μ g/g), carotenoids (17.6 to 39.6 mg/100 g), dietary fiber, B vitamins, vitamin C, calcium, and other essential nutrients with good bioavailability.²⁷ MO leaf powder (MOLP) has been shown to improve maternal health and increase birth weight in randomized controlled trials. It enhances iron metabolism and supports better absorption of iron, while its antioxidant properties help mitigate

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stress during pregnancy.²⁸ Other studies also indicate that combining MO plus royal jelly (MRJ) can address oxidative stress and anemia in mothers, leading to increased weight and length of newborn babies.^{29–32}

Previous studies have shown that small sample sizes have limited most research on the benefits of MRJ for anemic pregnant women. It is necessary to conduct more comprehensive studies to explore the effects of MRJ supplementation among a broader range of pregnant women, using larger and more representative sample sizes. Additionally, there is a lack of empirical evidence examining the impact of pregnancy on the normal age of delivery (37 to 42 weeks) and the placenta weight of the newborn. Therefore, this study aimed to assess the effect of MRJ capsules on the gestation age and placenta weight of newborns in Indonesia. The study intends to address the gaps identified in the current body of knowledge by providing insights into the effects of nutritional supplementation on maternal and neonatal health parameters.

MATERIALS AND METHODS

Ethical Consideration

The study adhered to the principles of the Helsinki Declaration, received ethical clearance, and obtained approval from the Hasanuddin University Public Health Research Ethics Committee with recommendation number 5517/UN4.14.1/TP.01.02/2023 on October 3, 2023. Informed consent was obtained from all participants before the study.

Study design and setting

This study employed a quasi-experimental design with a two-group post-test-only setup in the Banggai district, Central Sulawesi province, Indonesia (0.957091°S and 122.558593°E).

Study participant and sampling

The current study's population comprised all expectant mothers residing within two distinct sub-districts: Batui Selatan, which hosted 126 pregnant women, and Mailong, which hosted 116 pregnant women. The study uses a purposive sampling method from a formula to compare two different populations in numerical research. The calculation indicates that 80 pregnant women from each sub-district, a total of 160 pregnant women overall.

Inclusion criteria for participation in the study were rigorously defined. Eligible participants were required to be in their second trimester of pregnancy, in good health, free from any pathological conditions related to pregnancy, and devoid of specific medical conditions such as gestational diabetes, serious illnesses, or mental health disorders. Furthermore, participants must express a willingness to partake in the study and provide signed informed consent. Conversely, the exclusion criteria were delineated to omit any participants who relocated to another area, abstained from supplement intake for one week, or refused to continue with the prescribed supplement regimen.

Data collection and tool

The data collection process was meticulously carried out through collaboration with healthcare professionals, specifically midwives or nutritionists. This collaboration involved utilizing respondent demographic data sheets alongside specific questionnaires designed to filter data pertaining to maternal anthropometry and hemoglobin levels. The study carefully measured various factors related to pregnancy outcomes, such as the gestation age at delivery and the PW. The measurements were taken within 48 hours after childbirth using standardized methods to guarantee accuracy and consistency. Each subject was measured twice to ensure precision, and the average of these measurements was recorded for analysis.

Mailong District will receive MRJ, containing 490 mg of MOLP and 10 mg of royal jelly, as the intervention group, while the South Batui District will receive Multiple Micronutrient Supplement (MMS) as the control group. Both groups will take one capsule or tablet per day for six months (24 weeks). To ensure compliance, the researcher will monitor daily consumption over the six months through WhatsApp reminders and weekly check-ins by midwives and/or nutritionists. Compliance and side effects will be recorded using forms. Notably, no pregnant women reported side effects such as allergies or diarrhea during the study. Additionally, any unconsumed intervention materials will be reviewed weekly, and the researchers will assess participant adherence to inclusion criteria after each intervention week.

Statistical data analysis

The data analysis was performed using the Statistical Program for Social Science (SPSS) application version 28 for Windows, provided by IBM Corp., Armonk, N.Y., USA. Chi-square/Fisher's exact cross-tabulation analysis and a univariate model were conducted at a significance level of $p < 0.05$. The Kolmogorov-Smirnov test was applied to verify the normality of data distribution, with a normal value of $p > 0.05$. Mann-Whitney test was used for bivariate analysis to assess the variables between the intervention and control. The Analysis of Covariance (ANCOVA) was also employed to adjust for potential confounders. Statistical significance set at $p < 0.05$.

RESULTS

Table 1 illustrates the characteristics of the participants in the second trimester of pregnancy. A total of 160 pregnant women were involved in this study, with 86.9% being 20–35 years old. A majority, 60.9%, had completed Senior High School education, while 88.1% were housewives. Furthermore, 67.5% were multiparous, 85% of the participants had normal tension, 95% had a normal MUAC, and 53.8% were obese.

The cross-tabulation test results indicate comparable in both groups ($p > 0.05$), except for statistically significant differences between the two groups in BMI ($p=0.031$). In her previous pregnancy, most pregnant women gave birth normally (98; 61.3%). This time, she also had a normal delivery (142; 88.8%). Most of the babies in this study had normal weight (149; 93.1%) and length (153; 95.6%). The results of the cross-tabulation test also showed that all data related to the pregnancy outcomes were similar ($p > 0.05$) (Table 2).

In Table 3 of this study, we examined the independent variables of average gestational age and placental weight of neonates with MRJ and the MMS control groups.

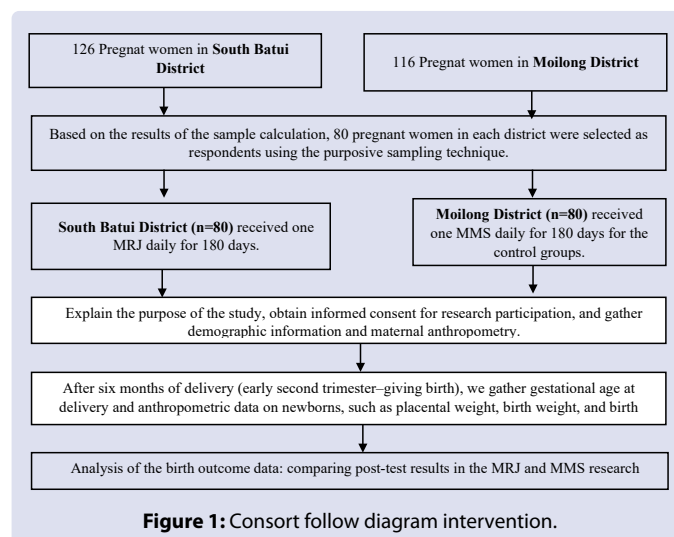


Figure 1: Consort follow diagram intervention.

Table 1: Characteristics of Respondents in both groups.

Variable	MRJ (n=80)		MMS (n=80)		P-value*
	n	%	n	%	
Age (Years)					
< 20	6	3.8	5	3.1	0.757
20–35	68	42.5	71	44.4	
> 35	6	3.8	4	2.5	
Education					
Elementary school (≤6 years)	7	4.4	15	9.4	
Junior high school (7–9 years)	18	11.3	10	6.3	
Senior high school (9–12 years)	49	30.6	48	30	0.152
College (> 12 years)	6	3.8	7	4.4	
Maternal Occupation					
Housewife	72	45	69	43.1	0.463
Occupation	8	5	11	6.9	
Parity					
Primipara	29	18.1	23	14.4	0.311
Multipara	51	31.9	57	35.6	
Blood Pressure					
Hypertension (>120/80 mmHg)	10	6.3	14	8.8	0.376
Normal (≥110/70–120/80 mmHg)	70	43.8	66	41.3	
MUAC					
CED (<23.5cm)	6	3.8	2	1.3	0.147
Normal (≥23.5cm)	74	46.3	78	48.8	
BMI					
Underweight (<18.5)	0	0	3	1.9	
Normal (18.5–23.9)	26	16.3	23	14.4	
Overweight (24.0–27.9)	6	3.8	16	10	0.031
Obese (≥28.0)	48	30	38	23.8	

Bold values denote statistical significance at the $P < .05$ level *Chi-squared/Fisher's exact test.

Table 2: Birth outcomes among pregnant women in both groups.

Variable	MRJ (n=80)		MMS (n=80)		P-value*
	n	%	n	%	
Previous birth history					
Nil	30	18.8	24	15	0.403
Normal	45	28.1	53	33.1	
Cesarean section	5	3.1	3	1.9	
Current birth					
Normal	72	45	70	43.8	0.803
Cesarean section	8	5	10	6.3	
Birth weight (gram)					
LBW (<2500g)	1	0.6	5	3.1	0.219
Normal (2500-4000)	77	48.1	72	45	
Macrosomia (>4000)	2	1.3	3	1.9	
Birth length (cm)					
Normal (≥47)	79	49.4	74	46.3	0.058
Short (<47)	1	0.6	6	3.8	

*Chi-squared/Fisher's exact test.

Table 3: Average Gestation Age and Placental Weight in both groups.

Variable	Mean (SD)	Min-Max	P value*	F (df)	P value ^a
Gestation Age					
MRJ (n=80)	39.63 ± 1.20	35-42	0.696	-	
MMS (n=80)	39.49 ± 1.55	35-42			
Placental Weight					
MRJ (n=80)	507.62 ± 79.87	320-720	0.007	0.081	0.001
MMS (n=80)	464.19 ± 84.27	300-680		(1,157)	

Bold values denote statistical significance at the $P < .05$ level; *Mann Whitney test, ^aANCOVA after controlling for BMI to analyze the variable of Placental Weight.

The Mann-Whitney test did not show a significant difference ($P = 0.696$) in the gestational age of delivery between the groups. However, a significant difference ($p < 0.05$) in the PW variable within the MRJ group was higher according to the Mann-Whitney test. Additionally, after adjusting for BMI in PW, the ANCOVA test indicated a significant difference ($P = 0.001$).

DISCUSSION

The main findings of this review study show that MRJ capsules had a more significant effect on placental weight in neonates compared to the MMS group in the general population, even after adjusting for different BMIs during pregnancy. In line with the study's findings in Sri Lanka, a positive correlation exists between placental weight and maternal BMI.¹³ Arundhana's (2018)³³ research also supports the beneficial effects of MO on the placenta. A study using linear regression found a significant correlation between the size of the placenta and birth weight, where each gram increase in placenta size resulted in an approximately 1.58 g increase in birth weight. The improved placental and fetal weight gain in the group supplemented with MO may be due to its ability to prevent DNA damage and reduce oxidative stress, demonstrating its positive impact on both placental and fetal development.^{32,34}

Malnutrition causes stress, and the World Health Organization (WHO) predicts a substantial increase in maternal stress and depression rates in developing countries.³⁵ Rahma (2023)³⁶ found that oxidative stress in placental tissue can lead to LBW in babies due to an imbalance of free radicals and antioxidants. High levels of malondialdehyde indicate oxidative stress, causing premature aging of the placenta and placental insufficiency, which affects fetal organ development and can result in ABO. Research indicates that MO can increase body weight and upper arm circumference in malnourished pregnant women, potentially preventing LBW and improving nutritional intake through antioxidants.^{23,30}

The research further elucidated that the instance of macrosomia observed could be attributed to the prolongation of gestation periods and amplification in weight respective to gestational age, consequently leading to a surge in mortality rates.³⁷ According to this study, the prevalence of macrosomia was 3.1% (5/160), which is lower than the 3.8% reported in a survey conducted in India. Some characteristics of mothers in this study were similar; for example, overweight and obese mothers and multiparous were associated with an increased risk of macrosomia in newborns.³⁸ Macrosomia significantly affects pregnancies in both developed and developing countries, with a prevalence ranging from 2-9% in LIMC.³⁹

The study found no post-term births, possibly due to the preference for cesarean section deliveries when pregnancies > 42 weeks. No significant gestational age differences were observed between the MRJ capsules and MMS groups, showing similar efficacy in term infant protection. The average gestational age was 39 weeks for both groups, supporting the beneficial effects of supplementation on fetal maturity. Deliveries at 39 weeks, aligned with full fetal organ maturity, are shown to reduce ABO.⁴⁰ Inducing labor at 39-40 weeks in uncomplicated pregnancies reduces risks of respiratory issues, meconium aspiration, low Apgar scores, and perinatal death, with studies consistently showing increased neonatal health risks at 37-38 weeks compared to 39-40 weeks.⁴¹⁻⁴³ Furthermore, a study by Wehby et al. (2022)⁴⁴ found that metabolic indicators linked to gestational age could predict a significant portion of the variance in academic performance, suggesting that these markers partly explain the differences in test scores between children born preterm and their full-term counterparts.

The first 1000 days of life are pivotal for a child's brain development and long-term health, with essential nutrients like protein, zinc, iron, and vitamins being crucial. Nutritional deficiencies during this period

can cause irreversible brain function deficits and raise the risk of conditions such as obesity, hypertension, and diabetes, stressing the need for multi-nutrient-rich diets for pregnant women, infants, and toddlers.⁴⁵ Inadequate nutrition can have lasting effects, highlighting the importance of ensuring pregnant women and their fetuses receive the necessary energy and nutrients for childbirth.²⁷ The "Barker Hypothesis" links poor fetal nutrition to a higher likelihood of chronic diseases in adulthood, suggesting early nutritional disruptions have long-term health impacts.⁴⁶ Addressing malnutrition is critical for achieving global Sustainable Development Goals (SDGs) by 2030 and "Indonesia Emas 2045", aiming to significantly reduce malnutrition among pregnant women, infants, and toddlers.⁴⁷

This study is the first to examine the effects of MRJ and MMS administration during the second trimester of pregnancy using a large group of participants. The research showed that both groups followed the treatment until delivery and had similar effects on pregnancy outcomes such as gestational age and placental weight. The effectiveness of MRJ and MMS interventions may be primarily due to the high adherence to both treatment methods. Additionally, the use of a 24-week supplementation strategy in pregnant women has been shown to reduce the risk of adverse birth outcomes in the studied groups, highlighting the potential benefits of such interventions in prenatal care.

The study has a few limitations. First, it only focuses on the week of delivery of the newborn baby, even though it is usually also assessed by birth weight that does not correspond to gestational age at birth, known as 'Small for Gestational Age (SGA).' The term "SGA" is limited in Indonesian medical and academic circles, and there is a lack of data on its prevalence in Indonesia. Although approximately 6% of babies are estimated to be born with LBW when their weights are recorded, nearly 27% of all live births are considered SGA in LIMC.⁴⁸ Secondly, demographic data from husbands and the economic status of both groups were not well documented, and the sex of neonates was also not reported due to difficulties obtaining data from participants. Lastly, in the 24-week study program, ABO were significantly reduced in both groups due to the supplementation intervention. However, the study did not investigate both groups' eating habits or food intake. This lack of examination could explain the occurrence of LBW and macrosomia, along with the impact of maternal BMI, which was a confounding variable in this study.

CONCLUSIONS

The study suggests that MRJ and MMS interventions are feasible and well-tolerated in preventing ABO related to newborns' gestational age and placental weight. These findings support the need for adequately powered studies on non-pharmacological monitoring interventions using MRJ in pregnant women. Future research endeavors must approach the interpretation of MRJ and MMS dosages with caution, particularly in light of the methodological limitations identified within this study concerning the prevalence of macrosomia among overweight and obese pregnant women. Subsequent studies must aim to replicate these findings within populations of first-trimester pregnant women, or even those prior to pregnancy, while incorporating a thorough analysis of demographic variables, including paternal data, socioeconomic status, and the neonate's sex, to evaluate their impact on pregnancy outcomes comprehensively.

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CONFLICTS OF INTEREST

There are no conflicts of interest.

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