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Research Article

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Effectiveness and Safety Profile of Oral Zinc Supplementation in Preterm or Low Birth Weight Infants: A Comprehensive Systematic Review from Developing Countries' Perspectives

Rafi Alfian Razan*, Safira Shafa Rachmah Hartawan and Kartika Nurrosyida

Faculty of Medicine Universitas Airlangga/Dr. Soetomo Academic General Hospital, Surabaya, Indonesia

***Corresponding author**
Rafi Alfian Razan, Faculty of Medicine Universitas Airlangga/Dr. Soetomo Academic General Hospital, Surabaya, Indonesia.

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ABSTRACT

Background: Zinc is essential for physiological functions, however preterm and/or low birth weight (LBW) infants have low zinc storage. This study aims to assess the effectiveness of oral zinc supplementation on preterm and LBW infants in Low and Middle-Income Countries (LMICs), as evidence on its health outcomes remains unclear.

Objectives: Zinc is essential for physiological functions in preterm and/or low birth weight (LBW) infants. However, recent guideline from WHO states oral zinc supplementation as a conditional recommendation with low certainty evidence. This study aims to assess the effectiveness and safety profile of oral zinc supplementation on preterm and LBW infants in developing countries, as evidence on its health outcomes remains unclear.

Methods: This study was conducted according to PRISMA 2020. We used PubMed and ScienceDirect to conduct a literature search published until January 2025.

Results: A total of 3071 preterm or LBW infants from 9 RCTs were included; 1589 of them received oral zinc treatment. Nine studies reported better growth parameters in the zinc group. The morbidities, such as BPD, NEC, ROP, and IVH, also mortality rate were reported to be lower in the zinc group.

Conclusions: Oral zinc administration in preterm infants has been shown to improve growth, reduce morbidity and mortality incidence.

Keywords: LBW, Developing Countries, Preterm, Zinc

Introduction

Preterm birth, which defined as babies who born alive before 37 weeks of gestational age, and low birth weight (LBW) infants, which defined as babies whose birth weight lower than 2.500g, are known as the most leading cause of neonatal death [1]. Globally, estimated 15 million babies are born preterm and more than 20 million babies have low birth weight. Over 81% of preterm infants and 96% of LBW infants were delivered in developing countries [2]. Preterm and LBW infants have much higher risk of morbidity and mortality than infants who born aterm and has normal birth weight [3,4]. Respiratory morbidities such as respiratory distress syndrome, dysregulation of temperature and glucose regulation, and infection are known to be the most short-term complication. Meanwhile, in the long term, they are at risk of growth and developmental disorder because they used to have feeding difficulties, linked to numerous of life-saving interventions in the NICU, Prolonged oxygen therapy for respiratory conditions (RDS, BPD), brain injuries (IVH, PVL, hypoxic injury), complex medical conditions like NEC and craniofacial abnormalities [5,6].

The management of short term complications in preterm infants involves umbilical delay cord clamping, stabilization of breathing by CPAP or intubation, and administering antibiotics to prevent and treat infections [7-10]. Additionally, surfactant, caffeine, steroids, and diuretics are used to prevent respiratory distress syndrome (RDS) and to reduce the duration of mechanical ventilation by enhancing respiratory drive, tidal

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volume, lung compliance, and decreasing total lung resistance, thereby minimizing the risk of oxygen toxicity [11,12]. On the other hand, growth and development disorder, as long-term complications of prematurity, must also be addressed. WHO recommends supplementation therapy to support growth and development in preterm and LBW infants by giving vitamin A, vitamin D, Calcium, phosphorous, probiotics, and zinc [13].

Zinc, an important micronutrient for cellular growth, cellular differentiation and metabolism, are found to be deficit in preterm and LBW infant [14,15]. The zinc deficiency in preterm infants occurs due to the early cessation of transplacental zinc transfer, leading to reduces zinc stores, causing low zinc storage [16,17]. Zinc deficiency are known to cause inhibition of linear growth, cell-mediated immune dysfunction, and cognitive impairment [18,19]. In response, WHO recommends administering 1-3 mg/kg per day of elemental zinc to preterm and LBW infants [13]. Recent studies shows that zinc supplementation decreased mortality causes and associated with improvement in short-term weight gain and linear growth, with no side effect were observed [15,20].

Zinc has been shown to improve in short-term weight gain and linear growth, primarily through its association with insulin-like growth factor 1 (IGF-1) [15,21]. IGF-1 are plays critical role in growth and development by promoting cell proliferation and differentiation and the primary mediator of growth hormone (GH) [22]. Early catch-up growth are beneficial for preterm and LBW infants, leading to faster linear growth and improves neurodevelopmental outcomes [23]. For this reason, zinc is essential for the growth and development of preterm and LBW infants.

Despite the recognized importance of zinc supplementation, WHO still classifies its recommendation for oral zinc supplementation in preterm and LBW infants as conditional, with low-certainty evidence [24]. This underscores the rationale for our study, which aims to give a recent update on the effectiveness and safety of oral zinc supplementation in reducing the incidence of mortality and morbidity and the impact on growth status in premature or low birth weight infants.

Methods

Conduct of Review

The results were reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guideline [25].

Search Strategy

We conducted a comprehensive search in PubMed and ScienceDirect from January, 1998 To January, 2025. Our search strategy included the following keywords: (“Preterm” OR “Premature” OR “Low birth weight”) AND (“Zinc”) AND (“Outcome” OR “Growth parameters” OR “Mortality” OR “Morbidity” OR “Length of stay”)

Inclusion Criteria

We collected studies from the 4 databases and removed duplicate publications with the Zotero program 5.0. Studies were first screened by title and abstract, based on the following eligibility criteria: (1) Experimental Study, (2) Study populations of infants with Low Birth Weight (LBW) and/or preterm status who have received zinc supplementation, (3) Studies outcome focused on growth parameters, serum zinc levels, morbidity, mortality, and length of hospital stay, (4) Full-text available in English and Indonesian. (5) Studies conducted in developing countries.

Preterm and Low Birth Weight Criteria

Preterm is defined as babies born alive before 37 weeks of pregnancy are completed. There are sub-categories of preterm birth, based on gestational age: extremely preterm (less than 28 weeks), very preterm (28 to less than 32 weeks), moderate to late preterm (32 to 37 weeks) [26]. Low birth weight has been defined by WHO as weight at birth of < 2500 grams (5.5 pounds) [27].

Anthropometric Measure

Anthropometric measurements of newborns reflect their general health, nutritional status and future survival by tracking trends in growth and development over time [28]. The CDC and the American Academy of Pediatrics AAP recommend using the 2.3rd and 97.7th percentiles of the WHO growth curves [29]. The main outcome of this study is growth parameters reporting mean body weight increment, mean body length increment, and mean head circumference.

Zinc Supplementation

Preterm and LBW infants are reported to be deficient in zinc, a mineral crucial for cellular growth, differentiation, and metabolism. WHO recommends 1-3 mg/kg daily of enteral zinc supplementation for preterm and/or LBW infants who have been fed enterally [24]. A recent Cochrane review reported the mean duration of supplementation was 182 (SD 142) days and the median duration was 141 (IQR 98-183) days [20].

Study Selection and Data Extraction

Titles and abstracts retrieved from the database were independently screened by three reviewers to identify relevant studies that met the selection criteria outlined above, who also independently assessed eligibility by further reviewing the full text. Disagreements were resolved through consultation with a fourth reviewer.

Three reviewers extracted data independently and discrepancies were identified and resolved in consultation with a fourth reviewer. Standardized and pre-tested data collection tables were used to extract data from included studies using the Systematic Review Data Repository [30]. The primary outcome of interest was the difference in mean increment of weight and length in anthropometric measures between the intervention and comparison groups. The secondary outcomes of this study were serum zinc level, morbidities, mortalities, and length of stay. The selection process is shown in the PRISMA 2020 flow diagram [Figure 1].

Study Quality Assessment

The risk of bias was specifically assessed using the Cochrane risk of bias (ROB) tool, based on criteria outlined by Schulz et al., as specified in the Cochrane Handbook for Systematic Reviews of Interventions [30,31]. Additionally, we use the National Institute of Health Quality Assessment Tool for observational studies. Three reviewers independently assessed the ROB quality of each

study. Any disagreements between the reviewers were resolved by the third reviewer.

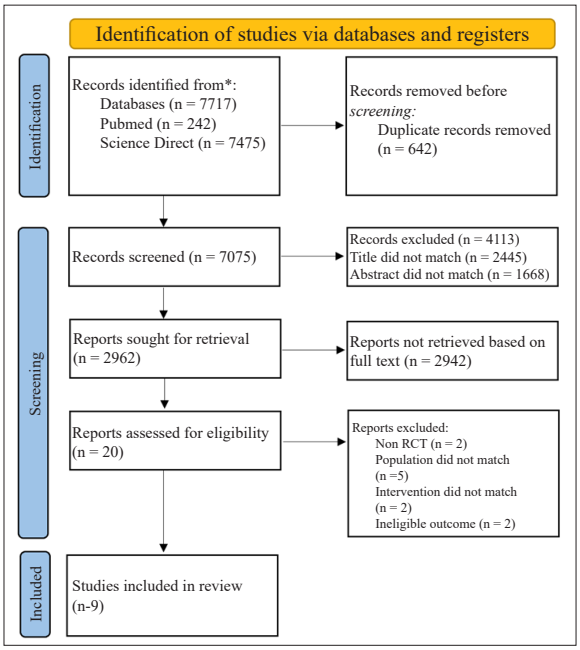

Figure 1: PRISMA flow chart of identification, screening, and selection of articles

Statistical Analysis

This search process generated 1491 articles from 4 databases. After removing duplicates, 1233 records were screened. Of those, 20 studies remained after removing those with unavailable full text. Finally, 9 studies were used [Table 1] for quantitative data synthesis. This process can be seen in our study selection flow chart [Figure 1].

Results

This study was conducted according to PRISMA 2020 [Figure 1]. We used PubMed, ScienceDirect, ProQuest, and Scopus to conduct a literature search published until May 2024 and total 11322 study was found. We excluded numerous of study because of no full text were available, didn't match with the inclusion criteria or didn't match the outcomes. Finally, thirteen RCT were included, involving 3439 Preterm or LBW infants, which 1775 of them were given zinc supplementation.

The risk of bias in these study were assessed with cochrane risk-of-bias tool for randomized-controlled trials (RoB 2) are shown in [Table 1]. Four out of nine study were rated low risk of bias, meanwhile four out nine study were rated high, and one study were rated with some concerns.

Table 1: Quality assessment using cochrane risk-of-bias tool for randomized-controlled trials (RoB 2)

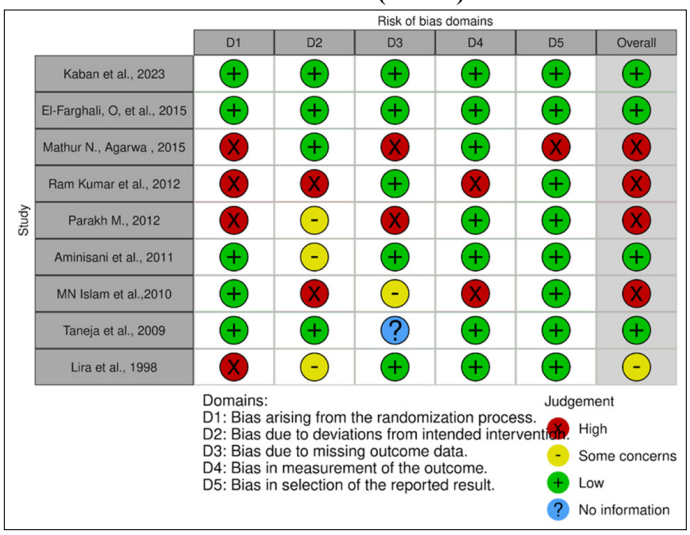

Table 2: The Characteristic of Subject

Reference	Study Design	Country	Total Participant, n(%)		Mean GA, weeks (SD)		Mean birth weight, Gram (SD)		Sex Male, n(%)		Journal Grade Quality
			Zinc	Placebo	Zinc	Placebo	Zinc	Placebo	Zinc	Placebo	
Lira et al., 1998	RCT	Brazil	139 (67)	66 (33)	38.9 (1.87)		2337 (152)		NR	NR	Some Concerns
Taneja et al., 2009	RCT	India	1026 (50)	1026 (50)	NR	NR	NR	NR	463 (45.1)	448 (43.7)	Low Risk
Islam et al., 2010	RCT	Bangladesh	50 (50)	50 (50)	NR	NR	NR	NR	NR	NR	High Risk
Aminisani et al., 2011	RCT	Iran	40 (52)	36 (48)	33.5 (2.5)	34.1 (2.1)	2109 (439)	2152 (434)	28(62)	20(44)	Low Risk
Parakh et al., 2012	RCT	India	75 (51)	74 (49)	35.75 (1.98)	35.14 (2.33)	1790 (200)	1720 (320)	NR	NR	High Risk
Kumar et al., 2012	RCT	India	46 (51)	45 (29)	34.8 (2.8)	34.6 (2.9)	1310 (185)	1268 (197)	23 (52.3)	20 (44.4)	High Risk
Mathur et al., 2015	RCT	India	50 (50)	50 (50)	33.4 (2.2)	33.4 (2.3)	NR	NR	33 (66)	32 (64)	High Risk
El-farghali et al., 2015	RCT	Egypt	108 (54)	92 (46)	34.95 (1.79)	35.28 (2.13)	1944.6 (307.25)	1991.73 (3017.76)	62 (57)	59 (64)	Low Risk
Kaban et al., 2023	RCT	Indonesia	78 (51)	76 (49)	31 (1.24)	30.8 (1.14)	1416 (290)	1372 (281)	34 (43.6)	34 (44.7)	Low Risk

From all study included, the subject characteristics from both group were found similar. The mean gestational age from all study were <37 weeks, mean birth weight were <2500 grams, and no significant differences in sex male. The growth parameter in this study, shown in [Table.3], were found to having greater result in height, weight, and head circumferences increment in the zinc group than the placebo group. Zinc serum levels were also found higher after supplementation in zinc group than the placebo group, that shown in [Table.3]. The morbidity events in this study, such as BPD, NEC, ROP, and IVH were reported to be higher in the placebo group [Table.3].

Table 3: Growth Parameter, Mean Zinc Serum Level, Morbidities, Mortalities, and Length of stay

Growth Parameter						
Reference	Mean Body Weight Increment, Mean (SD) gram		Mean Body Length Increment, Mean (SD) cm		Mean Head Circumferences Increment, Mean (SD) cm	
	Zinc	Placebo	Zinc	Placebo	Zinc	Placebo
Monthly						
Lira et al., 1998	4229 (1097)	4036 (1064)	62.77 (2.96)	62.86(2.35)	NR	NR
Aminisani et al., 2011	4295 (741)	3896 (865)	60.75 (3.2)	58.09 (4.1)	40.36 (1.39)	39.11 (1.51)
Parakh et al., 2012	4962 (750)	4770 (750)	62.27 1.73)	61.95 (1.73)	41.13 (1.53)	41.15 (1.3)
El-farghali et al., 2015	6867 (1247)	6350.6 (1134)	63.14 (3.93)	61.93 (3.49)	41.16 (2.17)	40.35 (2.17)
Weekly						
Islam et al., 2010	2343.8 (540.3)	2060.2 (396.3)	46.9 (2.6)	44.1 (2.8)	32.5 (1.2)	32.2 (1.3)
Daily						
Kaban et al., 2023	1424.6 (4.52)	1423.01 (6.44)	39.35 (0.58)	39.34 (0.41)	28.28 (0.52)	28.27 (0.48)

Mean Serum Zinc Level				
Reference	Mean Serum Zinc Level, Mean (SD) (mg/L)			
	Before supplementation		After supplementation	
	Zinc	Placebo	Zinc	Placebo
Taneja et al., 2009	63.4 (20.9)	64.7 (64.7)	100.2 (41.9)	73.3 (22.5)
Islam et al., 2010	62.1 (12.4)	63.1 (14.6)	105.8 (16.5)	82.2 (17.4)
Parakh et al., 2012	0.87 (0.39)	1.03(9.56)	0.88 (0.24)	0.83 (0.35)
Kaban et al., 2023	79.39 (26.68)	74.75 (24.79)	75.27 (24.79)	57.09 (18.77)

Morbidities, Mortalities, and Length of Stay		
	Zinc	Placebo
BPD, n(%)	19 (10)	25 (14)
NEC, n(%)	9 (5.14)	6 (3.48)
ROP, n(%)	1(0.5)	3(1.74)
IVH, n(%)	14 (8)	19(11)
Mortalities, n(%)	30 (2.3)	47 (3.6)
Mean Length of Stay (SD), days	35 (13.9)	42 (17.4)

Discussion

Zinc is essential for cellular growth, differentiation, and metabolism, making it a key element for preterm and LBW infants [24]. Nine studies from six countries were included in this review, all were RCTs and focused on research carried out in developing countries, such as Indonesia, Iran, Brazil, India, Egypt, and Bangladesh. Out of the 3439 preterm or LBW newborns in total, 1775 received oral zinc supplementation and 1664 others were given placebo with/without multivitamin other than zinc, such as iron, vitamin D, and others. The subject characteristics from both groups were found to be similar. Most infants were born at 37 weeks' gestation or earlier, only 1 study reported a mean gestational age of the subjects was 38.9 weeks (1.87). However, the mean birth weight of all subjects weighed <2500 g, ranging from 1372 to 2337 g.

Zinc deficiency has been well documented in hospitalized preterm and LBW infants. Preterm infants have lower absolute zinc reserves at birth, increased urine zinc excretion, and a reduced ability to absorb zinc from food compared to full-term babies [32]. Zinc plays a vital role in cell division and growth, neurotransmission, intestinal mucosal integrity, and immunological response [33,34]. The WHO recommends enteral zinc supplementation at a rate of 1-3 mg/kg per day of elemental zinc for preterm or LBW infants who are fed mother's own milk or donor human milk [24]. However, it was noted that there are limited data in literature as to the appropriate oral dose, timing of initiation, and its length of treatment. According to a recent Cochrane study in 2021, the median duration of supplementation was 141 (IQR 98-183) days, whereas the mean duration was 182 (SD 142) days.20 This systematic review addressed the effectiveness of oral zinc supplementation with growth outcomes and serum zinc levels, as well as morbidity and mortality. We found 6 studies addressing growth outcomes, 4 studies in serum zinc levels, and 2 studies in morbidity and mortality.

Cell differentiation and proliferation does not occur when zinc is deficient or none [34]. Six studies reported growth status measurements, 1 study each conducted daily and weekly measurements and 4 studies conducted monthly measurements. The growth status of the zinc and placebo groups did not differ significantly when compared in daily measurement (Table. 3). Variations in growth status began to appear in weekly measurements (Table. 3), with the subject in zinc group accomplished higher increment in body weight and body length (2343.8 (540.3) vs 2060.2 (396.3); 46.9 (2.6) vs 44.1 (2.8). When measurements were taken on a monthly basis, all studies reported significant differences on all 3 growth parameters (body weight, body length, head circumference) between the two groups, where the zinc group experienced a significant increase compared to placebo (Table. 3).

Fetal zinc accumulation primarily takes place after 24 weeks of gestation [35,36].The majority of zinc is stored in the fetal liver and later utilized during infancy to prevent deficiency [35]. Four studies reported mean serum zinc levels before and after supplementation. The typical range for a normal serum zinc level is 65–110 mg/L. However, it is important to note that there is currently no widely recognised standard for baby zinc levels [33]. All studies showed that subjects who were given zinc supplementation experienced a significant increase compared to

placebo (Table. 3). Mean serum zinc levels were also higher than placebo after supplementation (100.2 vs. 73.3; 105.8 vs. 82.2; 88 vs. 83; 75.27 vs. 57.09 mg/L), respectively and details shown in (Table. 3). Two studies even reported that subjects given placebo experienced a decrease in mean serum zinc level when not given supplementation.

Previous systematic reviews have shown that in addition to zinc can help optimize growth in children, also zinc can reduce the incidence of morbidity by preventing diarrhea and pneumonia, reducing the susceptibility and severity of infection in newborns [37]. In this systematic review, zinc was shown to have a lower percentage in reducing the incidence of morbidity in the form of BPD (10% vs. 14%), ROP (1% vs. 2%) and IVH (8% vs. 11%). The mean length of stay was lower in the zinc supplemented group (35 ± 13.9 vs. 42 ± 17.4). As a result of lower morbidity and shorter length of stay, the mortality rate was similarly lower (3% vs. 4%) in the zinc supplemented group.

To the best of our knowledge, this is the first systematic review to evaluate the evidence on zinc supplementation in preterm infants in developing countries. While the authors were not blinded to the data abstraction and analysis processes, the literature search, data extraction, and quality assessment were carried out independently by different investigators, thereby reducing the risk of selection bias.

Conclusion

Our study shows that administering Zinc supplementation to preterm and low birth weight infants in developing countries significantly enhances growth parameters (increases in weight, length, and head circumference), raises serum zinc, reduces the incidence of morbidity and mortality.

Disclosure

The authors declared no conflicts of interest. No funding was received for this study.

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