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IP Journal of Paediatrics and Nursing Science

Journal homepage: https://www.jpns.in/

Original Research Article

To study the effect of early zinc supplementation on growth of low birth weight infants- A randomised control trial

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ARTICLE INFO

Article history:
Received 28-12-2021
Accepted 20-01-2022
Available online 15-04-2022

Keywords:
Zinc
Supplementation
Weight and Infants

ABSTRACT

Background: The present study was carried out with aim to study the effect of early zinc supplementation on growth of low birth weight infants — A randomised control trial in the Department of Paediatrics at Government Medical College and Hospital, to study effect of zinc supplementation on LBW infants. The registered subjects were then randomized into Intervention (Group I, Case) and Non-Intervention (Group II, control) groups using computer generated random number technique. Cases (Group I) were given zinc supplements Syrup Zinc acetate (Syp. Zinconia 5ml=20mg) 2mg/kg single dose in morning at 8 a.m. daily and multivitamins drops 10 drops per day (Vit.A 375 μg, Vit.B1-B6, Vit.D 5μg) for duration of 6 weeks and Controls (Group II) were given multivitamins drops (Vit.A 375 μg, Vit.B1-B6, Vit.D 5μg) 10 drops per day for duration of 6 weeks.
Results: There was no significant difference in cases and controls in respect to males and females. No significant difference (p value >0.05) in pattern of intrauterine growth in cases and controls. Fifty percent of our study subjects in both group were of weight more than 1400 grams.
Conclusion: Zinc had significant effect on weight gain of pre-terms (AGA and SGA) and term AGA only at the end of 6 weeks. There was only significant effect on length in mean difference at 6 weeks when compared to at 48 hours. There was highly significant difference in supplement group (cases) in weight/length at 6 weeks with minimal or insignificant effect on chest circumference and head circumference.

1. Introduction

Zinc is an important trace element required by humans for overall growth and development. It is typically the second most abundant transition metal in organisms after iron and it is the only metal which appears in all enzyme classes. Zinc forms an essential part of various enzymes required in metabolic functions and immune system. Zinc is found in nearly 100 specific enzymes, serves as structural ion in transcription factors and is stored and transferred in metallothioneins.[1]

Zinc deficiency is common in young infants in the developing world and is associated with reduced immune competence and increased rates of serious diseases.[2] Low zinc concentrations have been observed in the cord blood of low birth weight (LBW) newborn babies (<2500 g) and birth weight has been shown to be highly correlated with cord zinc concentration in India.[3,4]

For several reasons, preterm infants have relatively high zinc dietary requirements and face special challenges to meet them. About 60% of fetal zinc is acquired during the third trimester of pregnancy, when fetal weight increases three-fold. Preterm infants have lower zinc reserves than

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https://doi.org/10.18231/j.ijpns.2022.003

term infants and because of immaturity, they may be less efficient at absorbing and retaining zinc for growth.[5]

Zinc supplements help prevent disease and reduce mortality, especially among children with low birth weight or stunted growth. Zinc deficiency has a negative effect on the endocrine system, leading to growth failure, among other clinical manifestations.[6,7] Zinc supplementation has been shown to reduce the rates of diarrhea and pneumonia, and to enhance physical growth of young infants.[8] Several studies conducted in various parts of the world have shown beneficial effect of zinc supplementation in early growth of preterm babies (small and appropriate for gestational age).[9,10] Keeping in view all of these facts, this study is conducted to evaluate efficacy of oral zinc supplementation on growth of preterm babies (small and appropriate for gestational age) and term small for gestational age babies in department of Paediatrics at Government Medical college and Hospital.

2. Materials & Methods

The present study was carried out in the Department of Paediatrics at Government Medical College and Hospital, to study effect of zinc supplementation on LBW infants. The present study was carried out in the educational year From November 2016 to September 2018. All preterm (AGA, SGA) and term SGA delivered in our or nearby hospital during time period of our study.

2.1. Study sample size

Total 280 (cases 140, control 140) who met our inclusion criteria were included in the study. Total 237 (case121, control 116) were followed up till total duration of 6 weeks. Of 140 cases 13 were lost during follow up, 4 were excluded due to unstable vitals during course of study and 2 expired. Of 140 controls, 17 were lost to follow up, 6 were excluded due to unstable vitals during course of study and 1 expired.

2.2. Inclusion criteria

1. All preterm infants between 28 weeks to 37 weeks weighing less than 2500 grams, who may be appropriate for gestational age (AGA) and small for gestational age (SGA) delivered at our hospital or at peripheral hospitals and primary health center.
2. All term infants (>37 weeks) whose weight were less than 2500 grams and delivered at our hospital or at peripheral hospitals and primary health center.
3. Mother of neonates who met above criteria, having no history of zinc supplementation during antenatal period.
4. Neonates who met above criteria and where admitted within the first 48 hours of life.

2.3. Exclusion criteria

1. Preterm infants with major birth defect or congenital deformities.
2. Preterm infants with unstable vital signs.
3. The parents did not consent to participate in the study.
4. Preterm infants born to mother who had taken zinc supplementation during antenatal period.
5. Preterm infant: Infant born before 37^{th} completed weeks of gestation 83.
6. Low Birth Weight (LBW): Infant birth weight less than 2500 grams 83.
7. Appropriate for Gestational age (AGA): Birth weight between 10^{th} and 90^{th} percentile on Lubchenco charts83.
8. Small for Gestational age (SGA): Birth weight less than 10^{th} percentile on Lubchenco charts 83.
9. **Case:** A preterm infant (AGA, SGA) of gestational age between 28 weeks and 37 weeks and term SGA (weight 1000 to 2499 grams) given supplement containing zinc (dose 2 mg/kg/day) orally with other multivitamins for 6 weeks.
10. **Control:** A preterm infant of gestational age between 28 weeks and 37 weeks and term SGA (weight 1000 to 2499 grams) given only multivitamins for 6 weeks.

3. Methodology

3.1. Informed consent

Written informed consent was taken from patients parents/guardians prior to enrollment in the study (See Annexure for Informed consent form).

3.2. Randomization

The registered subjects were then randomized into Intervention (Group I, Case) and Non-Intervention (Group II, control) groups using computer generated random number technique.

Cases (Group I) were given zinc supplements Syrup Zinc acetate (Syp. Zinconia 5ml=20mg) 2mg/kg single dose in morning at 8 a.m. daily and multivitamins drops 10 drops per day (Vit.A 375 μg, Vit.B1-B6, Vit.D 5μg) for duration of 6 weeks and Controls (Group II) were given multivitamins drops (Vit.A 375 μg, Vit.B1-B6, Vit.D 5μg) 10 drops per day for duration of 6 weeks.

3.3. Data collection

Each preterm (SGA & AGA) and term SGA babies delivered at our hospital whether admitted in NICU or kept in post-natal ward, as well as preterm (SGA & AGA) and term SGA babies referred from other hospitals within 48 hours of life were registered for study.

Detail history was asked with special emphasis on maternal history and previous obstetric history. Patients

were randomized as case and control and advised zinc supplementation and multivitamins to case population and only multivitamins to control population.

4. Results

Table 1: Distribution of study subjects according to sex.

Sex	Cases		Controls	
	No.	%	No.	%
Male	67	55.38%	59	50.8
Female	54	44.62%	57	49.2
Total	121	100%	116	100%

There was no significant difference in cases and controls in respect to males and females.

Table 2: Distribution of study subjects according to intrauterine growth.

Type of Intrauterine Growth	Cases		Control	
	No.	%	No.	%
AGA	67	55.37%	66	56.90%
SGA	54	44.63%	50	43.10%
Total	121	100%	116	100%

Test: Pearson Chi square test

Table shows that was no-significant difference (p value >0.05) in pattern of intrauterine growth in cases and controls.

Table 3: Distribution of study subjects according to birth weight.

Birth weight	Cases		Controls	
	No.	%	No.	%
<1000 gm	1	0.82%	0	0
1000- <1200 gm	4	3.30%	6	5.17%
1200 - <1400 gm	30	24.79%	24	20.68%
1400 - <1600 gm	22	18.18%	18	15.51%
1600 - <1800 gm	34	28.09%	32	27.58%
>1800 gm	30	24.79%	36	31.03%
Total	121	100%	116	100%

How's that about fifty percent of our study subjects in both group were of weight more than 1400 grams.

Table 4: Distribution according to difference in means of parameters at 6 weeks in comparison to at 48 hours.

Parameters	Cases (Mean ± S.D)	Controls (Mean ± S.D)	P value
Weight (gms)	710.25 ± 175.35	576.03 ± 135.68	<0.001*

Test: Pearson Chi square test.

*p value >0.05.

5. Discussion

In present study out of total 121 Cases (Group 1) 67 (55.38%) were male and 54 (44.62%) were female. Out of 116 Controls (Group 2) 59 (50.8%) were male and 57 (49.2%) were female.

There was no statistically significant difference in distribution of males and females in cases and control. Included total number of 100 cases and 100 controls. In the study 108 subjects were male and 92 were female i.e. 54% of them were male and 46% were female which was similar to our study.

101 very low birth weight (VLBW) infant. 91 subjects completed study. Total number of subjects in zinc supplement group were 46 and in placebo group were 45. In supplement group 23 (50%) and in placebo group 20 (44.4%) were male. 100 low birth weight subjects of appropriate for age weighing between 1000 – 2500 grams. Randomly allocated 100 LBW infants into either an intervention group or placebo and kept follow up from birth to 1 year of life. [11]

Distribution of study subjects according to birth weight. More than 50% of both cases and control had weight more than 1600 gms at birth. Only one subject (case) was weighing less than 1000 gms. Mean birth weight in gms.(±S.D.) in cases was 1590.661± 279.52 and in control was 1617.413 ± 270.39. There was no statistically significant difference in birth weight in cases and control. Similar mean (±SD) birth weight of 1789.50 ± 228.89gm for both cases and controls. [12] Mean birth weight of 1310 ± 185 gms in zinc group and 1268 ± 197 gms. In placebo group. Full term low birth infants, study subjects had mean (±SD) birth weight was 2337±152 g. Only 9 infants weighed < 2000 g. Sur et. al 2 study had Mean birth weight 2284 ± 160 g for the supplemented group and 2315 ± 168 g for the placebo group. Bueno et. al. 71 included 31 IUGR infants either to the zinc group (n = 14) with mean birth weight in gm.(S.D.) of 2,171 ± 253 gm or the placebo group (n = 17) with mean birth weight in gm.(S.D.), 249 ± 220 gm.

6. Conclusion

Out of total 237 study subjects 121 are cases and 116 are controls. Out of 121 cases 67 (55.38%) were male while 54 (44.62%) were female. Out of 116 controls 59 (50.8%) were male while 57 (49.2%) were female.

Zinc had significant effect on weight gain of preterm (AGA and SGA) and term AGA only at the end of 6 weeks. There was only significant effect on length in mean difference at 6 weeks when compared to at 48 hours. There was highly significant difference in supplement group (cases) in weight/length at 6 weeks with minimal or insignificant effect on chest circumference and head circumference.

7. Source of Funding

None.

8. Conflict of Interest

The author declares that there is no conflict of interest.

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Cite this article: Kundalwal A, Patel J, Gaikwad S. To study the effect of early zinc supplementation on growth of low birth weight infants- A randomised control trial. *IP J Paediatr Nurs Sci* 2022;5(1):10-13.