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COMPARISON OF GROWTH PARAMETERS OF PRETERM NEONATE WITH AND WITHOUT ZINC SUPPLEMENTATION

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Abstract:

Preterm birth is the most widely recognized reason for death among babies around the world. Around 15 million infants are preterm every year (5% to 18% of all death). In Pakistan, zinc deficiency is an emerging health problem as about 20.6% children were found to have serum zinc level<60 µg/dl.

Objective: *To compare mean weight and mean length of preterm neonates with and without zinc supplementation.*

Study Design: *Randomized controlled trial and non-probability sampling technique.*

Setting: *The study was conducted in Department of Pediatrics Unit-I, Neonatology section, Mayo Hospital Lahore.*

Duration of Study: *6 months from approval of this study*

Methodology: *After approval of study from IRB, 200 neonates who met the inclusion criteria were included in the study. After taking informed consent, demographic variables (name, age, gestational age at birth, gender, contact number) were obtained. Weight and length of neonates was measured at baseline. Then neonates were randomly allocated into two groups A & B by using computer generated random number. Group A: Neonates were given oral zinc supplementation in dose of 2 mg/kg/day (in ml) zinc supplement. Group B: Neonates were not given any zinc supplementation. Mothers were advised to give exclusive breast feeding and bring babies after 1 month of initial presentation. Further follow up visit was at 4 months postnatal age. The weight, length of neonates was measured at 4 month age (as per operational definition). Those patients missed any follow up were excluded from the study. All data was entered in specially designed performa (attached).*

Results: *The sample size of this study was dependent on the availability of participants in this regard, a sample of N=200 cases was recruited for this present study but only N=100 cases of each group (N=50 of with zinc supplementations) (N=50 without zinc supplementation) were enrolled during a period of total 60 days with 80% power of test, 5% margin of error, 95% confidence level and taking magnitude of weight i.e. 2779±638.7 grams with zinc supplementation and 2474.6±441.8 grams without zinc supplementation in preterm neonates. Independent sample t- test was used to compare results.*

Conclusion: *We concluded that there is no significant difference between growth of preterm neonates with zinc supplementation & without zinc supplementation.*

Keywords: *preterm neonates, weight, length, zinc supplementations*

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INTRODUCTION:

Preterm infants are at increased risk of death acute and long-term morbidity often associated with nutritional compromise and impaired growth with about 18 million preterm babies born each year worldwide. The burden is disproportionately concentrated in Africa and Asia where about 85% of all preterm births occur (31%) and 54% respectively. [1,2]Preterm and low birth rate (LBW) babies may have impaired zinc status due to low body stores limited capacity to absorb and retain micronutrients coupled with increased endogenous losses associated with organ immaturity high nutrient demand to support catch-up growth and inadequate intakes because exclusive breastfeeding does not compensate for increased demand due to prematurity. A significant proportion of children born prematurely showed growth retardation in childhood thus suggesting the need for a close clinical follow-up to determine their growth potential and implement effective intervention strategies Zinc an essential trace nutrient has important function to play in growth, reproduction, tissue repair and cellular immunity. Many studies have indicated that a negative Zinc balance exist in preterm and small for gestational age infants until approximately 36 weeks of gestation.[3]In Pakistan, zinc deficiency is an emerging health problem as about 20.6% children were found to have serum zinc level<60 µg/dl[4], Preterm infants have high zinc deficit and higher dietary requirements as 60% fetal zinc is acquired during third trimester of pregnancy[5] Zinc deficiency has a negative effect on endocrine system leading to growth failure among other clinical manifestations. [5]Animal studies had shown that material zinc deficiency has long-term effect on the growth, immunity and metabolic status of the surviving off spring [6] Clinical trials have found zinc supplementation effective for inducing growth in short children with zinc deficiency and that body zinc clearance tests facilitate detection of marginal zinc deficiency. Moreover oral zinc supplementation given in a dose of 9mg reduces morbidities and mortality in preterm neonates to half as compared to those who didn't receive zinc supplementation. [7] A study conducted in Bangladesh found that weight and length were comparable in both group of preterm neonates i.e. with and without zinc supplementation significant difference in weight gain and increment in length were found between two groups ($P < 0.05$). The mean weight after 6 weeks of follow-up was 2779.0±638.7 grams with zinc supplementation (n=50) while 2474.6±441.8 grams without zinc supplementation (n=50). The length after 6 weeks of follow-up was 50.3±2.8cm with zinc supplementation while 47.4±3.2 cm without zinc supplementation. [8]

The rationale of this study was to compare the growth parameters with and without zinc supplementation in preterm neonates. Literature has shown that zinc supplementation can help in development and growth of neonates born before completion of gestational period and neonates can grow healthier like other term babies. We are not able to find any regional and local study regarding zinc supplementation in preterm neonates. Through this study we intend to find out effect of zinc in growth of preterm neonates on large sample size.

MATERIAL AND METHODS:

This randomized control trial was conducted in the Department of Pediatric Medicine Unit-1, Neonatology section, Mayo Hospital Lahore, six months after approval from the hospital ethical review committee. Preterm neonates (as per operational definition with age 7-21 days of either gender and preterm neonates who are on breast feeding (not receiving bottle feed) were included in the study.

Preterm neonates were defined as neonates born before completion of 37 weeks gestation (as assessed by Ballard scoring). Growth parameters will be measured by weight in grams on electronic digital scales in patients with and without zinc supplementation at admission and then after 4 months and length centimeters on infant meter in patients with and without zinc supplementation at admission and then after 4 months.

Hypothesis: there is difference in growth of preterm neonates given zinc supplementation as compared to those without zinc supplementation. Neonates with major birth defect or congenital deformities (on clinical assessment) with unstable vital signs (Pulse > 120/min R/R>60) and neonates with systemic disease like CHD, sepsis (TLC>11,000 and <4000/mm^3) were excluded from the study.

Preterm neonates who are small for gestational age having birth weight <1500 grams (on clinical examination and neonates on bottle feed or on mixed feeding were excluded from the study. Size of sample depends on the time provide. In this regard, a sample of 200 cases, 100 cases of each group were enrolled from the Department of Pediatric Unit-1, Neonatology section, Mayo Hospital Lahore during a period of 60 days with 80% power of test, 5% margin of error, 95% confidence level and taking magnitude of weight i.e. 2779±638.7 grams with zinc supplementation and 2474.6±441.8 grams without zinc supplementation in preterm neonates.

200 neonates who met the inclusion criteria were included in the study. After taking informed

consent, demographic variables (name, age, gestational age at birth, gender, contact number) were obtained. Weight and length of neonates was measured at baseline. Then neonates were randomly allocated into two groups A & B by using computer generated random number. group 1: neonates were given oral zinc supplementation in dose of 2 mg/kg/day (in ml) zinc supplement and group 2 neonates were not given any zinc supplementation. Mothers were advised to give exclusive breast feeding and bring babies after 1 month of initial presentation. Further follow up visit was at 4 months postnatal age. The weight, length of neonates was measured at 4 month age (as per operational definition). All data was entered in specially designed Performa (attached).

The data was entered and analyzed through SPSS (Statistical Package for Social Science) version 20. Quantitative variable like age, length and weight were presented as mean and standard deviation. Qualitative variables like Gender were presented as frequency and percentage. Both group were compared for mean weight, length by using independent sample t-test ≤0.05 was considered as statistically significance. Data was stratified for gender and socio-economic status to deal with effect modifies. Post-stratification independent sample t-test was applied and P-value ≤0.05 was taken as significant.

RESULTS:

The frequency analysis of age which showed that N=96 participants were included between 28 to 30 age range, N=71 between age range of 31 to 33 and N=33 were between 34 to 36. Table No. 1

The frequency analysis of gender total N=300 participants were included in this study male were n=182 and female were n=118. (Table No. 2)

Sample of N=99 participants were belong to low socio economic status, N=65 were belong to middle class background and N=36 participants were belong to high class background. (Table No. 3)

Table 1: Age Distribution (n=200)

Gestational Age(Weeks)	
N	200
Mean	31.2250 ± 2.04 weeks

Table 2: Distribution of Gestational Age (n=200)

	Frequency	Percent
28 – 30	96	48.0
31 – 33	71	35.5
34 – 36	33	16.5
Total	200	100.0

Table 3: Sex distribution of study cases (n=200)

	Frequency	Percent
Male	122	61
Female	78	39
Total	200	100.0

The distribution of weight at admission among study case N=35 participants had 1500g to 2000g, N=89 had 2000g to 2500g, N=43 were 2500g to 3000g and N=33 were 3000g to 3500g weight at time of admission.(Table No. 4).

Table 4: Socio Economics Status (n = 200)

	Frequency	Percent
Low< 20,000 Rs/month	99	49.5
Middle 20 – 60000 Rs/month	65	32.5
High> 60,000 Rs/month	36	18.0
Total	200	100.0

The frequency distribution of weight gain after 4 months N=68 participants were 3000g to 3500g, N=77 were 3500g to 4000g, N=44 were 4000g to 4500g and N=11 participants were 4500g to 5000g. (Table No. 5)

Table 5: Distribution of weight at admission (n=200)

	Frequency	Percent
1500g - 2000g	35	17.5
2000g - 2500g	89	44.5
2500g - 3000g	43	21.5
3000g - 3500g	33	16.5
Total	200	100.0

The frequency distribution of length of participants at time of enrolment N=70 were 30cm to 35cm, N=58 were 35cm to 40cm, N=41 were 41cm to 45 and N=31 were 46cm to 50cm. (Table No. 6)

Table 6: Distribution of weight gain after 4 month (n=200)

	Frequency	**Percent**
3000g - 3500g	68	34.0
3500g - 4000g	77	38.5
4000g - 4500g	44	22.0
4500g - 5000g	11	5.5
Total	200	100.0

The frequency distribution of gain in length of participants after 4 months duration:
N=12 were 35cm to 40cm, N=67 were 41cm to 45cm, N=76 were 46cm to 50cm, N=38 were 51cm to 55cm and N=7 were 56cm to 60cm. (Table No. 7)

Table 7: Distribution of length of participants time of enrolment (n = 200)

	Frequency	**Percent**
30cm – 35cm	70	35.0
35cm -40cm	58	29.0
41cm – 45cm	41	20.5
46cm -50cm	31	15.5
Total	200	100.0

The frequency distribution of gain in length of participants after 4 months duration. N=12 were 35cm to 40cm, N=67 were 41cm to 45cm, N=76 were 46cm to 50cm, N=38 were 51cm to 55cm and N=7 were 56cm to 60cm.

Table 8: Distribution of gain in length of participants after 4 months (n=200)

	Frequency	**Percent**
35cm - 40cm	12	6.0
41cm -45cm	67	33.5
46cm - 50cm	76	38.0
51cm -55cm	38	19.0
56cm - 60cm	7	3.5
Total	200	100.0

The mean for the weight at time of enrolment is 1.4915 and standard deviation is .48754 in gender male. The mean for the Weight after 4 months is 3.747 and standard deviation is .38490 in gender male. The number of participants in each condition (N) is 123. The P-value in our table is 0.575. (Table No. 9)

Table 9: Comparison of weight in gender (n=123) Male

	N	Mean	Std. Deviation	P-value
Weight at time of enrolment	123	1.4915	.48754	.575
Weight after 4 months	123	3.7447	.38490	

The mean for the weight at time of enrolment is 1.4526 and standard deviation is .45825 in gender female. The mean for the Weight after 4 months is 3.8149 and standard deviation is .36265 in gender female. The number of participants in each condition (N) is 77. The P-value in our table is 0.201. (Table No.10)

Table 10: Comparison of weight in gender (n=77) Female

	N	Mean	Std. Deviation	P-value
Weight at time of admission	77	1.4526	.45825	.201
Weight after 4 months	77	3.8149	.36265	

The mean for the weight at time of enrolment is 1.5551and standard deviation is .49997 in low socioeconomic status. The mean for the Weight after 4 months is 3.7859 and standard deviation is .41632 low socioeconomic status. The number of participants in each condition (N) is 99. The P-value in our table is 0.124. (Table No. 11)

Table 11: Comparison of weight Low Socioeconomic Status (n=99)

	N	Mean	Std. Deviation	P-value
Weight at time of admission	99	1.5551	.49997	.124
Weight after 4 months	99	3.7859	.41632	

The mean for the weight at time of enrolment is 1.4192and standard deviation is .43100 in middle socioeconomic status. The mean for the Weight after 4 months is 3.8131 and standard deviation is .33915 low socioeconomic status. The number of participants in each condition (N) is 65. The P-value in our table is 0.056. (Table No.12)

Table 12: Comparison of weight Middle Socioeconomic Status (n=65)

	N	Mean	Std. Deviation	P-value
Weight at time of admission	65	1.4192	.43100	.056
Weight after 4 months	65	3.8131	.33915	

The mean for the weight at time of enrolment is 1.3639and standard deviation is .45866 in higher socioeconomic status. The mean for the Weight after 4 months is 3.6583 and standard deviation is .30995higher socioeconomic status. The number of participants in each condition (N) is 36. The P-value in our table is 0.047. (Table No.13)

Table 13: Comparison of weight in higher socioeconomic Status (n=36)

	N	Mean	Std. Deviation	P-value
Weight at time of admission	36	1.3639	.45866	.047
Weight after 4 months	36	3.6583	.30995	

The mean for the weight at time of enrolment is 33.67and standard deviation is 4.223 in gender male. The mean for the Weight after 4 months is 37.81 and standard deviation is 3.970in gender male. The number of participants in each condition (N) is 123. The P-value in our table is 0.854. (Table No. 14)

Table 14: Comparison of Length (n=123) Male

	N	Mean	Std. Deviation	P-value
Length at time of enrolment	123	33.67	4.223	.854
Length after 4 months	123	37.81	3.970	

The mean for the weight at time of enrolment is 33.56and standard deviation is 3.733 in gender female. The mean for the Weight after 4 months is 37.60 and standard deviation is 3.499 in gender female. The number of participants in each condition (N) is 77. The P-value in our table is 0.996. (Table No. 15)

Table 15: Comparison of Length (n=77) Female

	N	Mean	Std. Deviation	P-value
Length at time of enrolment	77	33.56	3.733	.996
Length after 4 months	77	37.60	3.499	

The mean for the weight at time of enrolment is 33.22and standard deviation is 3.754 in low socioeconomic status. The mean for the Weight after 4 months is 37.42 and standard deviation is 3.589 in low socioeconomic status. The number of participants in each condition (N) is 99. The P-value in our table is 0.257. (Table No.16)

Table 16: Comparison of length in Low Socioeconomic Status (n=99)

	N	Mean	Std. Deviation	P-value
Length at time of enrolment	99	33.22	3.754	.257
Length after 4 months	99	37.42	3.589	

The mean for the weight at time of enrolment is 33.65and standard deviation is 4.033 in middle socioeconomic status. The mean for the Weight after 4 months is 37.42 and standard deviation is 3.589 in middle socioeconomic status. The number of participants in each condition (N) is 65. The P-value in our table is 0.124. (Table No. 17)

Table 17: Comparison of length in Middle Socioeconomic Status (n=65)

	N	Mean	Std. Deviation	P-value
Length at time of enrolment	65	33.65	4.033	.124
Length after 4 months	65	37.69	3.661	

The mean for the weight at time of enrolment is 34.69and standard deviation is 4.646 in higher socioeconomic status. The mean for the Weight after 4 months is 38.64 and standard deviation is 4.060 in higher socioeconomic status. The number of participants in each condition (N) is 36. The P-value in our table is 0.73. (Table No. 18)

Table 18: Comparison of length in Higher Socioeconomic Status

	N	Mean	Std. Deviation	P-value
Length at time of enrolment	36	34.69	34.69	.073
Length after 4 months	36	38.64	4.060	

DISCUSSION:

Preterm babies found to be on greater risk of retarded growth, long-term morbidity and to mortality. These factors are associated with their compromised nutrition and deprived growth. Preterm neonates are especially weak because of preterm delivery and low birth weight. The burden of premature births disproportionately concentrated in Africa and Asia where about 85% of all preterm births occur (31%) and 54% respectively.

Zinc is one of the essential trace metals for many physiological functions and plays an important role in growth and reproduction. It is also essential to maintain immune system. The preterm babies have zinc in very inadequate amount which may cause the growth stunting and may affect their physical activities. These infants have very limited stored energy and needs an adequate supply of nutrient. The reason of having low growth rate is mainly associated with the lower capacity of body to store and absorb nutrients because of premature organ development. Preterm infants need zinc in higher amount as 60% fetal zinc is acquired during third trimester of pregnancy and due to their early birth they do not get the required dietary amount which causes low birth weight and affect their growth. Babies born with low weights have been noted to have low zinc concentrations in cord blood, and zinc deficiency in childhood is associated with reduced immune-competence and increased infectious disease morbidity.

In Pakistan zinc deficiency reported as a serious health problem. With accordance to the study presented in 2014 by Tasleem Akhtar et al, overall prevalence of zinc deficiency in neonatal babies was 27.8%, of whom 8.8% women were severe zinc deficient.

In previous study, oral zinc supplementation decreases morbidities and mortality in preterm neonates and this study reported by GianlucaTerrin et al. Zinc supplementation for preterm low birth weight babies is found effective to enhance the growth in early months of life. It can result in a considerable reduction in infectious disease mortality. [28]

This study gave a strong evidence to the previous researches by showing the association between the zinc supplementation and improved growth by comparing two groups in which one group of preterm babies were provided the zinc supplementation for 4 months to saw the growth pattern while others did not received zinc as a nutrient.

According to this Study, 200 preterm patients, 100 cases in each group were placed. In group 1 Neonates were given oral zinc supplementation in dose of 2 mg/kg/day (in ml) zinc supplement and group 2, Neonates were not given any zinc supplementation and 95% confidence interval and taking weight 2779±638.7 grams with zinc supplementation and 2474.6±441.8 grams without zinc supplementation in preterm neonates. Zinc supplementation for preterm low birth weight babies is found effective to enhance the growth in early months of life. Which is more similar to the results found in the study presented in 2010 by Siddika, M. et al. according to their conclusion Zinc supplementation for preterm low birth weight babies is found effective to enhance the growth in early months of life.

Majority of the patients 89(44.5%) weigh between 2000g to 2500g at time of enrolment while 35(17.5%) patients weight were (1500g to 2000g), 43(21.5%) patients weight were (2500g to 3000g) and 33 (16.5%) patients weight were (3000g to 3500g) before supplementation. But after 4 months of zinc supplementation the weight of most of the patients 77(38.5%) were between 3500g to 4000g while 68(34.0%) patients weight were (3000g to 3500g), 44(22.0%) patients weight were (4000g to 4500g) and 11(5.5%) patients weight were (4000g to 5000g). which showed that in preterm babies zinc intake improved growth and development. This fact also has been noted in the study presented in 2009 by Islam MN et al. [9]

This study considered 200 patients in which, 123(61.5%) patients were “male” and 77(38.5%) patients were “female”. 64(32%) Male Patients belong to group 1 and 36(18%) Female Patients belong to group 1. 59(29.5%) Male Patients belong to group 2 and 41(20.5%) Female Patients belong to group 2. The ratio between male and female was 123:77. There was no association between sex and group as per (P-value > 0.05). which showed that preterm birth and growth retardation due to insufficient zinc intake is not specific to any gender as it have the same chance to occur in both genders which is also reported in previous studies.

Out of 200 patients, 23(11.5%) patients were the gestational age of 28 weeks, 7(3.5%) patients were the gestational age of 29 weeks, 66(33.0%) patients were the gestational age of 30, 1(0.5%) patients were gestational age of 31, 67(33.5%) patients were the gestational age of 32, 3(1.5%) patients were gestational age of 33, 15(7.5%) patients said that they were gestational age of 34, 14(7.0%) patients were gestational age of 35, 4(2.0%) patients were gestational age of 36. According to this study most patients belong to gestational age 30 and 32 which was also reported earlier in the study presented by Nicolas E. Embleton et al in 2001. [10]

The length and weight of children measured at the time of enrolment and then length and weight of preterm neonates after 4 months. On comparing of preterm neonate with zinc supplementation and without zinc supplementation, there was some difference between average weight of preterm neonate with zinc and without zinc supplementation as per the P-value 0.042 < 0.05, and there is no difference between average length of preterm neonates with zinc supplementation and without zinc supplementation as per the P-value 0.503 > 0.05.

CONCLUSION:

Even though all of the advancements in research, growth problem is still a frequent and major problem among preterm infants. If preterm infants accumulate significant nutrients such as zinc in the first few weeks of life that then they can survive with the better health condition. This study made a contribution to explain the fact that zinc supplementation helps to improve the growth pattern between the preterm babies which will help them to live a normal life with good immune system and proper body functions. According to this study zinc intake reduces the risk of growth retardation within the neonates born with less than 33 weeks' gestation period. This lead to accept the fact that zinc is a significant and beneficial supplement in reducing death and disease causing reasons in preterm neonates. The statistical analysis with respect to tight confidence intervals and extremely low P values indicates that additional zinc supplementation-controlled trials are unnecessary if a suitable zinc product is available. The growth retardation can only cured by providing the infants with the adequate amount of nutrients especially zinc and to minimize the occurrence of preterm birth in different regions of the world but due to unawareness and socio-economic condition of some countries the preterm birth is a still significant health problem, not only in terms of associated mortality but also with regard to short- and long-term morbidity and financial implications for health-care systems. With the consideration of all the facts in this study we can conclude that there is average difference between growth of preterm neonate with zinc supplementation and without zinc supplementation and zinc supplementation for preterm low birth weight babies is found effective to enhance the growth in early months of life. While this fact has been reported in different studies as well as in this study, there is still a need of long term follow up studies to evaluate the beneficial effect of zinc supplementation on growth of preterm babies and to provide the awareness among the mothers having this problem with their babies.

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