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Original Research Article

Effectiveness of Albendazole in Improving Nutritional Status of Pre-School Children in Rural Area of Madhepura, Bihar

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Abstract

Objective: To study the clinical efficacy of albendazole in improving the nutritional status of pre-school children.

Methods: Fifty Anganwadi centers were randomly selected for the trial. Included were registered resident children between 2 to 5 years of age with informed and written parental consent. The intervention group received 400 mg of albendazole powder every six months while the placebo group received same quantity of calcium powder. Enrolled children were contacted once in six months from January 2022 to June 2022 and given treatment. The outcome measure were change in the proportion of underweight (weight for age <-2.00z)and stunted (height for age <-2.00z) children.

Results: There were 610 and 451 children in the albendazole and placebo groups, respectively. Mean age at recruitment was 31.8 months (SD: 9.7). Follow-up and compliance in both the groups was >95%. During the 2 year follow-up, the proportion of stunted children increased by 11.44% and 2.06% in the placebo and albendazole groups, respectively, and the difference was 9.38% (95% CI 6.01% to 12.75%; p value <0.0001). Direct fecal smear was positive for the ova of ascaris in 41.2% and 55.3% children in the albendazole and placebo groups respectively at the end of the study (p value <0.001).

Conclusions: Six monthly albendazole reduces the risk of stunting in pre-school children.

Keywords: Anganwadi centers, Albendazole, Calcium powder

Introduction

The majority of pre-school children in India are malnourished[(1)] and also worm infested[(2)]. The most common geohelminth infesting pre-school children in the urban slum is ascaris[(3)] and similar findings have been reported from various developing countries[(1,4-5)]. Infestation with ascaris has been associated with malnutrition[(4,6-9)] and may be its cause. We hypothesized that periodic deworming of children will result in an improvement of their nutritional status . We used albendazole for deworming because it has been found to be effective against almost all the geohelminths[(10-13,15)], with cure rates of >90% for Ascaris lumbricoides.

Material and Methods

The study was carried out in the rural area of Madhepura, Bihar, from July 2022 to December 2022. This setting has been described in details elsewhere[(14)]. Through the national Integrated Child Development Scheme (ICDS) each slum has an "Anganwadi Center" (AC) with one health worker ("Anganwadi" Worker) and caters to the needs of children under 6 years of age. The "Anganwadi" worker maintains an almost complete list of the beneficiaries.

Eligible children were those between 2 to 5 years of age who were registered with the "Anganwadi" worker and whose parents consented to the study. No parent refused to participate. It was assumed that majority of children below 2 years of age would not be harboring intestinal parasites, and

therefore would not be benefited by deworming. Hence children only above 2 years were eligible for the study.

There are approximately 100 Anganwadi centres in Madhepura rural area. Of these 50 were randomly selected for this study. A list of all the eligible children from a rural area was obtained. Maintaining the order in which the Anganwadi worker within a rural area listed it, each child was allocated a serial number. Those with odd or non-zero endings numbers, approximately 40% of all eligible candidates, were assigned to the placebo and the rest to the intervention group. Thus, from 50 slums 1061 children were enrolled in the study. Personal interviews of mothers were done to collect information on the socio-economic status of the family and history of passage of worms in the preceding one month in the enrolled child.

As a part of the usual health maintenance, children are supposed to be weighed once every six months. Our intervention was linked with these visits. Children randomized to the intervention group were given 400mg of albendazole powder every six months for 2 years, while those in the placebo group received the same quantity of calcium powder. The two powders looked and smelled almost the same but were different in taste. The mothers dissolved the powder in water and the children were made to swallow it in front of the project officer. The mothers were blinded to the intervention type but not the providers.

The primary outcomes were changes in the prevalence of underweight and stunted children over two years. "Underweight" was defined in relation to the World Health Organization's standards (National Center for Health Statistics) for nutritional anthropometry as those with a weight for age `z' score <_2.00. Stunted were children with height for age `z' score <-2.00. Change in the prevalence of wasting was also assessed, where wasting was defined as weight-for-height <-2.00 `z' score.

Secondary outcomes were weight and height gains, hemoglobin levels, illness episodes, developmental status and passage of worms. The number of deaths in each group also has been reported, although death was not a main outcome for this study.

Children were weighed on a electronic digital weighing scale that could measure up to the nearest 10 grams. Inter and intra-observer variation was less than 5%. The calibration of the machine was validated against standard weights of 10 kg and 20 kg weekly. The co-relation coefficient was 0.96 with the standard weights. Height was measured using the Leicester height measure stadiometer. The infantometer and stadiometer could measure to a minimum of 1 mm. Inter and intra-observer variation was less than 5%. The correlation between the initial weight measure and the validated measure was 0.91. If the two readings of the same child differed by more than 200g, a mean of the two was used in the analysis. The hemoglobin levels were estimated by visual color estimation using Sahli's hemoglobinometer[16] in the rural area.

Mothers were asked to recall passage of roundworms by the child in the six months before entering the study. They were instructed to collect fresh fecal specimen of the child in a labeled glass vial provided. The intervention was given only after the stool specimen had been collected. Within 8 hours of collection direct smear examination was done for ova of helminths and saline iodine staining for the detection of protozoa[17]. The intensity of infestation was not estimated. The technician was blind to the randomization status.

The sample size calculations were based on a 60% prevalence of underweight or stunting at baseline. Assuming that there would be no change in the proportion of underweight or stunted children with the placebo and a 15% improvement with albendazole, then to detect this difference with an alpha of 5%, power of 80% and 1:1 randomization we would need 500 children in each arm of the trial.

Epi Info6 statistical software[18] was used for nutritional anthropometry calculations. Anemia was defined as hemoglobin less than 11g/dl[19]. The proportion of underweight, stunted, wasted and anemic children in the two groups of the trial at baseline were compared in the two arms of the trial using the Chi-square test.

Univariate comparison of weight and height gains over 2 years in the two groups was done by student's test. The differences in the weight and height gains between the albendazole and the placebo group were considered in the primary analysis since each child served as a control for him/her self in both the arms.

Within each arm, changes in the proportion of underweight, stunted and wasted children at the end of the trial were compared using Chi square test. The difference in the change of proportion of the nutritional indices between the placebo and the albendazole arms along with the 95% confidence interval of the difference was calculated.

Results

We recruited all the eligible children between the ages of 2 to 5 years (n=1061) registered with the anganwadi worker from 50 randomly selected Anganwadi centers. Of these 52% were males and 48% were females.

We enrolled 610 and 451 children in the albendazole and placebo groups, respectively. At the end of the study, 9 children in the albendazole and 7 in placebo group had been lost to follow-up. Seventy-six and seventy two per cent children in the albendazole and placebo groups, respectively, took the intervention in front of the project officer.

Most of the mothers of children who were sent home with the medicine said that the child took it. On combining the number of children who took the intervention in the community and those who took it at home, we found 95.9% and 96.9% compliance in the albendazole and placebo groups, respectively.

The mean age was 31.8 mo (SD 9.7 mo); sixty seven per cent subjects were Hindus and thirty three per cent Muslims. The characteristics of children in the two group of the trial are shown in Table 1. A similar proportion of children in the intervention and control groups were undernourished and had a history of worms at the time they entered the study. Of the 1061 children, 285 (26.9%) were siblings of which 97 (34%) and 71 (24.9%) were randomized to albendazole and placebo groups, respectively, and 117 (41.1%) were in either of the two groups.

Table 1: Characteristics of the Participants at Enrollment and at the End of the Study

	Placebo	Albendazole
No. enrolled	451	610
Siblings	71 (15.7)	97 (15.9)
Sex, M	233 (51.7)	316 (51.8)
At enrollment		
Age (mo)	31.1±9.2	31.1±8.7
Weight (kg)	10.2±2.1	10.1±2.1
Height (cm)	81.7±8.7	82.0±8.1
Hb (g/dl)	9.5±.9	9.5±0.9
Anemic	411 (91.1)	553 (90.7)
Field defecation	224 (49.7)	320 (52.5)
H/o worms^{+}	22 (4.9)	16 (2.6)
Ascaris +ve	48 (10.6)	76 (12.5)
After 2 years		
No. of children at last follow up	444	601
Weight (Kg)	12.84, 1.94	12.71, 1.93
Height (cm)	92.21, 8.08	92.01, 8.02
Weigh gain (kg)	2.68, 1.20	2.63, 1.34
Height gain (cm)	10.35, 5.1	9.94, 4.9
Hb (g/dl)	9.67, 0.65	9.67, 0.66
Ascaris +ve (%)$^{++}$	55.3	41.2
	(95%CI50.6%-59.9%)	(95% CI 37.0%-45.2%)

Figures in parantheses indicate percentages. Values depict either mean ± SD or number.
* P = 0.03; $^{+}$ P = 0.05 $^{++}$ <0.0001.

The weight and height and changes in these two parameters over the study period are shown in Table 1. The main outcome measures, the risk reduction of being underweight or stunted, are summarized in Table 2.

Table 2: Assessment of Change in Nutritional Indices over 2 Years

	Placebo		Albendazole		Difference (95% CI)
	N	%	N	%	%
At Enrollment					
Underweight	299	66.30	418	68.52	_2.22(_ 8.12 to 3.68)
Stunted	247	54.77	364	59.67	_4.9 (_ 11.11 to 1.31)
Wasted	81	17.96	114	18.69	_0.73 (_ 5.62 to 4.17)
End of Study					
Underweight	241	54.27[a]	325	54.08[c]	0.19(_ 6.12 to 6.50)
Stunted	294	66.22[a]	371	61.73[d]	4.49 (_ 1.58 to 10.56)
Wasted	46	10.36[b]	68	11.31[a]	_0.95 (_ 4.95 to 3.05)
Per cent Difference (End minus beginning)					
Underweight	12.02		14.45		2.43 (_ 1.90 to 6.76)
Stunted	11.44		2.06		9.38 (6.01 to 12.75)
Wasted	7.6		7.37		_0.23 (_ 3.66 to 3.20)

Abbreviations:

For intra-group comparison of pre and post trial values

[a] = p value < 0.001; [b] = p value < 0.001; [c] = p value < 0.001; [d] = p value = 0.5

Discussion

The present study was a community based, randomized placebo controlled, single blind trial for assessing the clinical efficacy of albendazole in preventing underweight and stunting in pre-school rural area children. There was a statistically significant reduction in the proportion of children who become stunted at the end of 2 years with six monthly albendazole.

There were certain advantages and disadvantages of our community based study design. We found almost negligible migration out of the urban slums for the groups as a whole, so there was almost complete follow-up. However, being a single blind trial, the project workers did succumb to community pressure and occasionally changed the intervention type given. Sometimes children passed round- worms within a couple of days after ingestion albendazole and this unblinded the parents. Therefore, as expected the crossover were less from the albendazole to the placebo group than vice-versa. Crossover to the placebo group may be intentional on the part of the project officers to compensate for albendazole substitution in others as the total doses of interventions given to them were fixed. Since the trial was analyzed as intention to treat, these crossover biased the result towards finding no effect. However, since the study was single blind, there is a possibility of bias towards the positive side, despite taking all precautions to keep the primary hypothesis unknown to the field staff. Children between 2 to 5 years were included in the trial and hence the results of the work have to be validated for other age groups and different sites before generalization. The sample size for this study was based on categorical outcome. Over 2-year follow-up a statistically significant increase of 11.44% and 2.06% of stunting was noticed with placebo and albendazole, respectively. Demonstrating differences in the change of nutritional indices is more important than merely weight or height gains as the former can be directly translated into community benefits while the value of the latter two parameters in isolation is unclear. To detect a 0.5 cm difference in height gain with a standard deviation of 0.5 cm, a three times larger sample size would be required in each arm as compared to the current one[20]. Hence, the current study can neither prove nor disprove any effect of the intervention on height gain, a continuous outcome. Various workers from different countries have demonstrated a weight gain with albendazole[8,9] and other antilminths[2]. In another randomized trial of six monthly albendazole in pre-school children in the urban slums of Lucknow a 35% greater weight gain was noticed with albendazole[15].

Demonstrations of height gain with periodic deworming of children have been inconsistent[8,9,15]. From a policy perspective, changes in the community prevalence of stunting have hardly ever been measured as in the current study. The present study failed to demonstrate any improvement in the hemoglobin levels with periodic albendazole therapy.

We have found that with routine deworming the prevalence of fecal smear positivity for ascaris increased to 41.2% from a baseline level of 12.5%. This indicates high re-infection rates. In children with placebo, there was an increase of the prevalence of fecal smear positivity for ascaris from a baseline level of 10.6% to 55.3%. These prevalence rates in placebo group are in accordance to those found in the routinely dewormed group and may be indicative of high transmission rate. Since parents were neither encouraged or discouraged from de-worming their children, there is a possibility of underestimation of parasite prevalence in both the groups, but more so in the placebo. The data from the trial justifies mass deworming of pre-school children since about half of them are infested with round worms. Currently in the anganwadi centres supplemental diet is being used for improving the nutritional status of preschool children . Routine deworming can also be considered as an additional strategy.

A recent meta-analysis on the effects of deworming on nutritional and cognitive para-meters was done by the Cochrane Collaboration[21]. Meta-analysis showed small statistically significant effects on mean change in weight in single and multiple dose trials less than one year in duration but not in programs longer than one year. Narrative analysis indicates mixed and inconclusive results related to effect on cognitive performance. Although there is a general belief that treating intestinal parasite infections in children will improve growth and cognitive performance, there is no current evidence to quantify these effects[21].

Conclusion

We conclude that in the rural areas children routine deworming reduces the risk of stunting in preschool children.

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