RESEARCH PAPER

Effect of Green Banana *(Musa paradisiaca)* on Recovery in Children With Acute Watery Diarrhea With No Dehydration : *A Randomized Controlled Trial*

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Background: Cooked green banana (*Musa paradisiaca*) has been observed to be useful in reducing the duration of diarrheal illness in children.

Objective: To evaluate whether supplementation of cooked green banana shortens the duration of diarrhea in children with acute watery diarrhea with no dehydration.

Study design: Open label randomized controlled trial.

Participants: Consecutive children aged 9 months to 5 years who presented with acute watery diarrhea within 48 hours of onset of illness with no dehydration.

Intervention: Children in the control group received standard care, while those in the intervention group received cooked green banana in addition to standard care under supervision in the hospital for 72 hours, and then continued at home until diarrhea stopped or 14th day of illness, whichever is earlier.

Outcome measures: Proportion of children who improved at 72 hours of intervention (passing formed stools with normal frequency) was considered as the primary outcome and the incidence of complications such as dehydration, persistent diarrhea and secondary lactose intolerance were evaluated as the secondary outcomes.

Results: The proportion of children who recovered within 72 hours was significantly higher (62.4%) in the green banana group compared to the control group (47.2%) [RR 1.3 (95% CI 1.05-1.7), NNT=7].The number of children with complications such as dehydration and persistent diarrhea was also signi-ficantly less in the intervention group.

Conclusion: Supplementation of cooked green banana in the diet of children with acute watery diarrhea with no dehydration hastens their recovery.

Key words: *Duration, Management, Outcomes*.

Trial registration: CTRI/2017/05/008623

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Diarrhea is an important determinant of childhood mortality and also predisposes the child to under-nutrition [1,2]. Supportive measures such as adequate hydration (by frequent breast feeding, home available fluids and oral rehydration solution) and oral zinc therapy are the mainstay of management as per World Health Organization (WHO) [3].

Cooked green banana (*Musa paradisiaca*) is shown to have a beneficial effect in lessening the duration of diarrhea and dysentery [4,5]. The short chain fatty acids released from the resistant starch, a major constituent of green banana, has been demonstrated to increase the absorption of water and electrolytes from the large intestine and prevent complications such as dehydration [6]. Literature on green banana in diarrheal illness is sparse and is limited to resource-constrained countries like Bangladesh. Given the paucity of data from India, our objective was to evaluate whether supplementation of cooked green banana shortened the duration of diarrhea in children with acute watery diarrhea with no dehydration.

Accompanying Editorial: Pages 1108-1109

METHODS

This open label randomized controlled trial was conducted from June, 2017 to June, 2018, in the department of pediatrics of a tertiary care teaching hospital in India. Children aged 9 months to 5 years, presenting within 48 hours of onset of acute watery diarrhea (AWD) with no dehydration (based on WHO criteria) [3] and whose parents were willing to admit their children in the hospital for three days were considered for the study. It was ensured that the parents did not have any financial

burden due to the hospital stay. From among these, children who could not be fed orally, who were under-nourished (weight for age *Z* score <-2) [7], those having any concurrent or pre-existing severe illness, and those who had received any antibiotic or anti-motility agents in the last seven days were excluded. Children with blood in stool were also excluded. After getting written informed consent from the parents, one of the investigators randomized the eligible children into two groups based on block randomization with variable block size using computer-generated randomization sequence. Allocation conceal-ment was done using sequentially numbered, opaque, and sealed envelopes. All the investigators enrolled and assigned the participants to interventions. Blinding could not be done in view of the logistics involved. Assuming the proportion of children with formed stools at 72 hours (primary outcome) to be 60% in the control arm [4] and 80% in the intervention arm (absolute difference of 20%), the sample size estimated with a power of 90% and alpha error of 5% was 105 in each group. Considering a dropout rate of 20%, it was decided to recruit 125 children in each group.

Children in the Control group, received standard care for acute diarrhea (zinc sulphate 20 mg orally once daily for 14 days, plus frequent breast milk, if on breast feeding, plenty of home available fluids, such as rice *kanji*, butter milk or tender coconut water, ORS 10 mL/kg/loose stool, and regular diet). Children in Green banana supplemented diet (GB) group received standard care, as above, and cooked green banana, in addition. The raw green banana was boiled for ten minutes following which the skin was peeled and the pulp was mashed to semi-solid consis-tency using a spoon. The cooked green banana was offered either alone (with little salt for taste) or mixed with any other food of their choice; the dose of green banana was 50 g twice daily for children younger than 1 year, 100 g twice daily for those aged 1-3 years, and 100g thrice daily for those aged 3-5 years [4]. The green banana supplemented diet was continued until diarrhea stopped or till the 14th day of illness, whichever was earlier. Children who developed dehydration were managed as per WHO protocol [3]; other complications were treated uniformly as per the institutional protocol. Children who persisted to have diarrhea beyond 72 hours from the beginning of intervention were advised to continue the standard treatment at home. The parents of the GB group were also advised to give cooked green banana daily until cessation of diarrhea – the cooking method was explained to the parents prior to discharge. Compliance for home available fluids, ORS and zinc for both the groups and in addition cooked green banana for

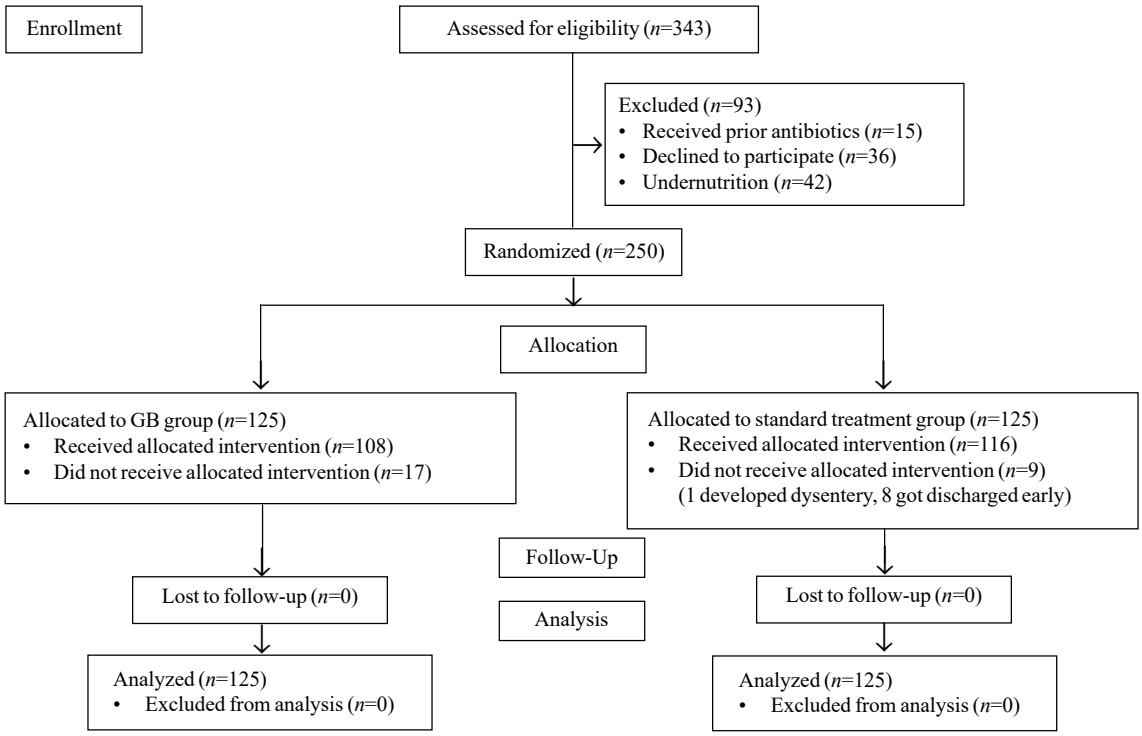


Fig. 1 *Consort flow diagram depicting study methodology.*

the intervention group was ensured by daily telephonic contact until the 14th day of illness and the details were collected. The parents were asked to bring the child for review if there were any concerns on telephonic discussion. Children with diarrhea persisting for more than 14 days were also reviewed again in the hospital.

The primary outcome assessed was the proportion of children who improved at 72 hours of intervention (passing formed stools with the usual frequency), as observed by the mother and verified by one of the investigators. The incidence of dehydration, persistent diarrhea (diarrhea persisting beyond 14 days), lactose intolerance (as evidenced by perianal excoriation and positive stool reducing substances test) and any other complications were evaluated as the secondary outcomes. The study was approved by the Institutional ethics committee, and the trial was prospectively registered in Clinical Trials Registry of India.

Statistical analyses: Data collection was done with the help of a semi-structured pretested proforma and was transcribed into Microsoft Excel spread sheet. Data analysis was done using the software STATA version 12. The baseline socio-demographic variables were compared between groups using chisquare test. An intention to treat analysis was performed. The proportion of children recovering within 72 hours, and the development of complications in both the groups were compared using the chisquare test. In addition, time to event analysis was carried out for recovery using Kaplan Meier survival graphs and the recovery time between the groups was compared using log rank test. All statistical testing was carried out at 5% level of significance.

Table I Baseline Characteristics of Children With Acute Diarrhea Enrolled in the Study (*N*=250)

Characteristics	*Green banana group (n=125)*	*Control group (n=125)*
Age, mo	23 (13.7)	22.8 (13)
Weight for Age		
-2 to -1 Z	72 (57.6)	67 (53.6)
1 to 0 Z	44 (35.2)	52 (41.6)
>0 Z	9 (7.2)	6 (4.8)
Current breastfed		
09-12 mo of age	25 (20)	20 (16)
13-24 mo of age	13 (10.4)	16 (12.8)
25-36 mo of age	1 (0.8)	0
Duration of illness[*]		
0-12 h	13 (10.4)	16 (12.8)
13-24 h	42 (33.6)	38 (30.4)
25-36 h	37 (29.6)	42 (33.6)
37-48 h	33 (26.4)	29 (23.2)
Fever[*]	46 (36.8)	42 (33.6)
Vomiting (1-3 times/d)[*]	32 (25.6)	37 (29.6)

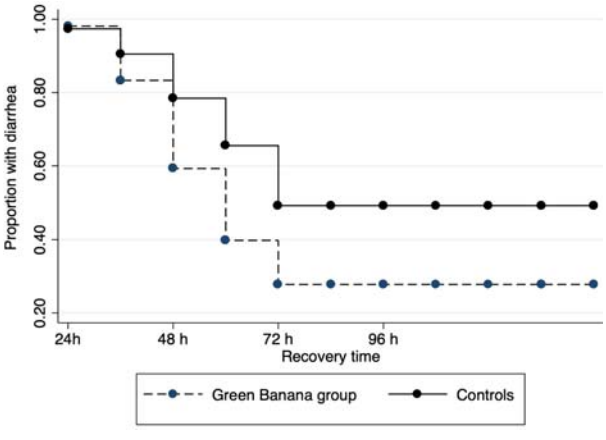
[*]*at presentation; All values in no. (%) except age in mean (SD); P>0.05 for all comparisons.*

RESULTS

Of the 250 children recruited, 108 children in the green banana group and 116 children in the control group completed the study (***Fig.* 1**). There was no significant difference between the groups with respect to the baseline demographic characteristics, socioeconomic status, duration of the illness (between the onset of illness and reporting for treatment), fever, vomiting and the prevalence of breastfeeding (***Table* I**). Children in the intervention group received GB diet for a median (IQR) duration of 3 (2) days (range, 2-14 day of illness). depending on the duration of diarrhea. The proportion of children recovering within 72 hours was significantly higher (62.4%) in the GB group as compared to the Control group (47.2%) [RR (95% CI) 1.3 (1.05-1.7), NNT=7; *P*=0.002] (***Table* II**). Moreover, on comparing the time to recovery using Kaplan Meier graph, the proportion of children with diarrhea at 72 hours was significantly less in the green banana group (***Fig.* 2**).

During the three days of stay in the hospital, none of the children in the two groups developed severe dehydration. Significantly higher number of children in the control group developed some dehydration (*P*=0.006) and persistent diarrhea (*P*=0.01) (***Table* II**). None of the children in either group developed any other complications, including acute kidney injury.

None of the children had any side effects to the cooked green banana (excessive vomiting or abdominal



GB: green banana.

Fig. 2 *Kaplan Meier graph showing recovery time in the two groups.*

Table II Recovery From Acute Diarrhea and Complications in the Study Population (*N*=250)

Parameter	*Green banana group (n=125)*	*Control group (n=125)*	*Risk ratio (95% CI)*	*P value*
Recovery within 72 h	78 (62.4)	59 (47.2)	1.3 (1.05-1.7)	0.02
Dehydration within 72 h	2 (1.6)	13 (10.4)	0.15 (0.03-0.7)	0.006
Persistent diarrhea	4 (3.2)	15 (12)	0.3 (0.1-0.8)	0.01
Secondary lactose intolerance	1 (0.8)	5 (4)	0.2 (0.02-1.7)	0.2

Values in no. (%).

pain). Fifteen children (12%) in the green banana group refused to eat the specified amount of green banana despite trying multiple times. The green bananas were purchased daily from the local market and the approximate cost was three rupees (INR) per child per day.

DISCUSSION

This open label randomized control trial documented faster recovery following supplementation of green banana in the diet of under-five children with acute watery diarrhea with no dehydration. Our findings are in agreement with the pioneering work from Bangladesh [4], documenting recovery both on day 3 and day 7 after supplementation with green banana among 2968 children with acute diarrhea in a cluster randomized field trial. The serial assessment over 72 hours of all the recruited children in the hospital by physicians is one of the strength of the current study. The present study also demonstrates the lesser number of children developing dehydration in the intervention group highlighting stool volume reduction, as also shown previously [5]. Moore, *et al*. [8] noted a six-fold higher incidence of persistent diarrhea in children with diarrhea lasting for more than seven days. We noticed only 30% children receiving intervention to develop persistent diarrhea. Hence, early initiation of green banana supplemented diet, as in our study, may limit the number of diarrhea days and may lower the progression to persistent diarrhea.

The exact mechanism of action of green banana in acute watery diarrhea remains elusive. The widely recognized hypothesis involves the role of resistant starch in diarrhea. Resistant starch, constituting 83.7% of green banana [9], is refractory to enzyme hydrolysis in the small intestine, and passes unaltered to the colon where it is acted upon by the normal commensals to produce short chain fatty acids (SCFA), which are the primary mediators of the beneficial activity [10]. The cytoprotective properties of SCFAs play an active role in the maintenance of the tight junction integrity through increased claudin expression [11], regeneration of infected epithelium by stimulation of the mucosal transglutaminase activity [12] and positive jejunotrophic effects through autonomic nervous system [13]. All these mechanisms assist in the absorption of sodium and water. Moreover, an exclusive Butyrate-HCO_3^- transporter mechanism in absorption of sodium and water is also demonstrated [14]. Also, by promoting the growth of the commensals [10] and by producing antimicrobial peptides at the epithelium [15], SCFAs also exert non-specific antimicrobial activity. This has been demonstrated by *in vitro* studies [16] and in animal studies [17].

Our study has few limitations. The cooked green banana was mixed with salt for better palatability. This could have altered the electrolyte intake and might have had a potential effect on the outcome as well. As post-discharge compliance was assessed by daily telephonic conversations, objective measurement was not possible during that period. Despite mothers' efforts, acceptability of green banana was a major problem (12%) in our study. Introduction of green banana as a complementary food in infancy, addition of flavors of infant's choice to the green banana diet [18], or use of palatable preparations of green banana such as papads are suggested [19].

Although oral rehydration solution is the mainstay of treatment in children with acute watery diarrhea, we feel that green banana diet with its above-mentioned properties has a promising role, especially in developing countries. In conclusion, this open label randomized controlled trial highlights the role of cooked green banana supplemented diet as a useful adjunct to standard treatment (ORS, home available fluids and zinc) in the management of acute watery diarrhea with no dehydration.

Ethical clearance: Institutional ethics committee of MGMCRI, Puducherry; ECR/451/Inst/PO/2013/RR-16 dated 08/06/2016.
Contributors: DG, AC: conceptualized, designed the study and finalized the manuscript; KK, BB, PJ, PS: collected, compiled the data and helped in analyzing and drafting the manuscript. All have approved the final draft.
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WHAT IS ALREADY KNOWN?

- Addition of cooked green banana in the diet is beneficial in diarrheal illness.

WHAT THIS STUDY ADDS?

- Cooked green banana diet in addition to standard treatment reduces the duration of illness and lessens the chances of complications in under-five children with acute watery diarrhea without dehydration.

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