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Green banana-supplemented diet in the home management of acute and prolonged diarrhoea in children: a community-based trial in rural Bangladesh

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Summary

OBJECTIVE To determine the effectiveness of green banana in the home management of acute (<7 days) or prolonged (≥7 days) diarrhoea at the community level.

METHODS A cluster randomized field trial was conducted among 2968 Bangladeshi rural children 6–36 months old. Wards (villages) were randomly assigned to either a standard care group or a standard care plus green banana group where mothers were instructed to add cooked green banana to the diets of diarrhoeal children. Through a village-based surveillance system, diarrhoeal morbidity data (severity, duration, compliance) were collected for 14 days. Treatment effects were determined by analysing cumulative probability of cure by testing Cox proportional hazards models and relative risk (RR).

RESULTS The cumulative probability of cure was significantly ($P < 0.001$) different in children receiving GB for both acute [hazard ratio (HR) = 0.63 (95% CI: 0.56–0.67)] and prolonged diarrhoea [HR = 0.38 (95% CI: 0.26–0.59)]. The recovery rates of children with acute diarrhoea receiving GB (*vs.* control) were significantly more by day 3: 79.9% *vs.* 53.3% [(RR) = 0.47, 95% CI: 0.41–0.55], ($P < 0.001$) and day 7: 96.6% *vs.* 89.1% (RR = 0.32; 0.22–0.46), ($P < 0.001$). Children with prolonged diarrhoea receiving green banana had significantly higher recovery rates by day 10: 79.8% *vs.* 51.9% (RR = 0.42; 0.23–0.73), ($P < 0.001$) and day 14: 93.6% *vs.* 67.2% (RR = 0.22; 0.08–0.54), ($P < 0.001$).

CONCLUSION A green banana-supplemented diet hastened recovery of acute and prolonged childhood diarrhoea managed at home in rural Bangladesh.

keywords resistant starch, home management, primary care, diet therapy, antidiarrhoeal

Introduction

Diarrhoeal diseases remain an important cause of disability and death, especially among children in developing countries. Recent estimates suggest 1.5–2.0 million deaths because of diarrhoeal diseases occur among children less than 5 years of age worldwide (Black *et al.* 2010). Approximately 10% to 20% of acute diarrhoeal illness will evolve into prolonged (>7 days) or persistent (>14 days) childhood diarrhoea (Thapar & Sanderson 2004). These children have a higher risk of death and suffer from long-term complications such as malabsorption, malnutrition and growth failure (Thapar & Sanderson 2004; Black *et al.* 2010). The identification of effective, affordable and acceptable interventions for acute and prolonged diarrhoea management remains an important challenge.

Several cereal-based (rice, oatmeal, semolina, banana) and chicken-based diets have been found to be clinically useful in the management of childhood diarrhoea (Nurko *et al.* 1997), and the antidiarrhoeal effects of dietary fibre in children have also been reported (Brown *et al.* 1993). Green bananas have been a traditional remedy for many digestive disorders, including childhood diarrhoea. Recently, it was demonstrated in our in-patient facility at ICDDR,B that adding green banana to the diets of diarrhoeal children significantly hastened their clinical recovery, corrected abnormal mucosal permeability and improved nutrient absorption (Rabbani *et al.* 2001, 2004). The antidiarrhoeal action of green banana is thought to be mediated by its high content of amylase-resistant starch that upon reaching the colon is fermented into short-chain fatty acids, in turn stimulating colonic salt and water absorption (Binder 2010).

Given the promising results of our hospital-based studies with the GB-supplemented diets, the question arises whether this diet would be effective in the home

management of acute or prolonged childhood diarrhoea of mild to moderate severity. The purpose of this investigation was to determine the effectiveness of adding GB to conventional household diets in the management of childhood diarrhoea, specifically in reducing duration of illness.

Materials and methods

Study design

This was a cluster randomized field trial conducted in Mirsarai subdistrict in Bangladesh (Figure 1). After institutional and ethical approval, the study was carried out from April 2002 to December 2003. The unit of randomization was a cluster (administrative ward) that typically includes 2–3 adjacent villages with a population of about 3000. In Mirsarai, 72 wards were enumerated, 18 were excluded because they were too remote. Of the remaining 54 wards, 18 were randomly selected based upon permuted blocks of six. From the 18 wards, we randomly assigned 12 to a standard care group (comparison wards) and six to another standard care plus green banana diet group (treatment wards). Among the 12 comparison wards, six were randomly assigned to continue with standard diarrhoea care according to WHO guidelines (WHO 1995) if a

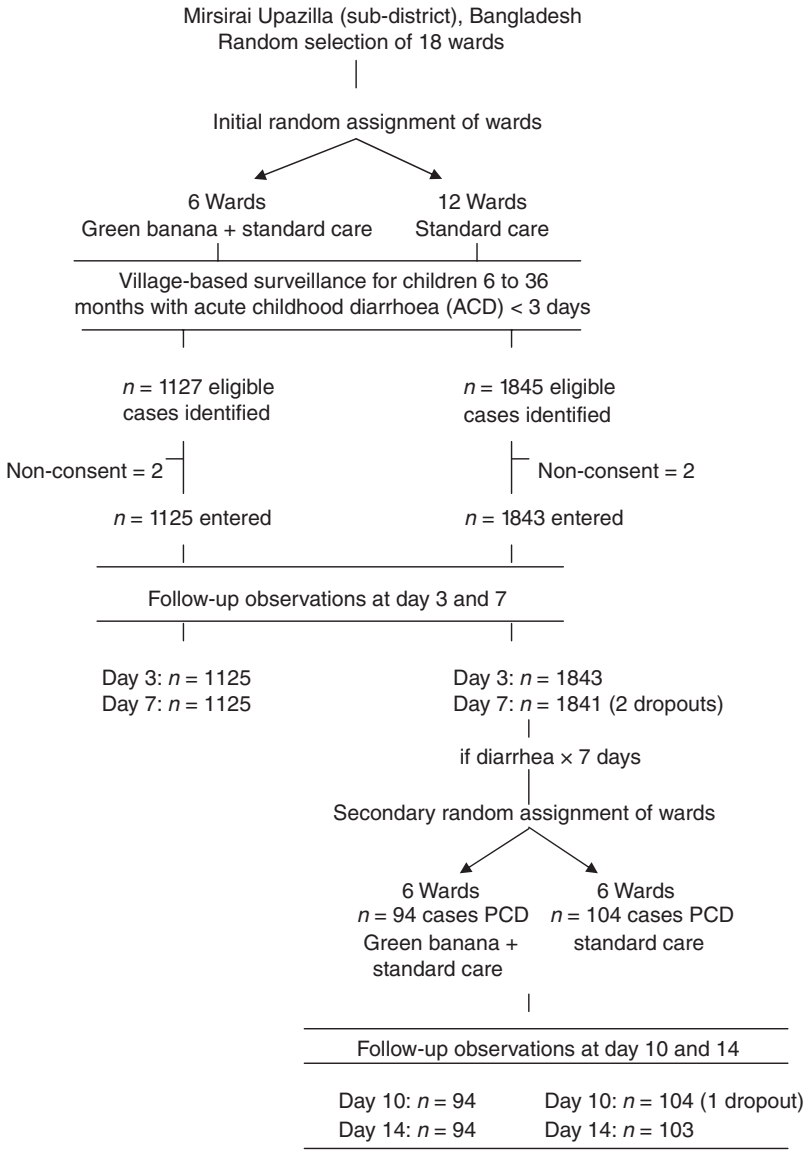

Figure 1 Trial profile.

child's illness continued for 7 days or more (prolonged childhood diarrhoea: PCD) and six wards received standard diet plus the green banana diet. Local representatives were informed of the purpose of the study and what would be required of households enrolled in the study.

Participants and procedures

Any child 6–36 months of age, residing in the study areas who was identified through a village-based surveillance with an active episode of acute childhood diarrhoea (ACD) of <3 days (72 h) duration as reported by the caregivers was eligible for the study. Excluded from the study were children who required hospitalization and those with important comorbidity (tuberculosis, malaria). Children were not excluded on the basis of nutritional status alone. Children meeting these criteria, whose parent provided informed, written consent for participation were enrolled. Once a child had been entered into the study, instructions were given to all caretakers in the management of the child's illness in accordance with the WHO guidelines.

Every day, 60 local women workers contacted all participating households and asked the mothers about signs of diarrhoea of their children. Any diarrhoeal child identified was confirmed by the nearest field staff who interviewed the mother using a standardized questionnaire. In addition, a trained fieldworker visited each household twice weekly (every 3rd day) for 20 consecutive months to collect information on diarrhoeal morbidity and characteristics of illness. Baseline information collected included a history of the current and past illnesses, environmental hygiene and socio-demographic characteristics. Mothers were asked to report the time of first appearance of diarrhoeal stool, daily numbers of stools, passage of blood or mucus, history of vomiting, treatment given and other relevant information. The clinical assessment included vital signs, hydration status, lethargy and the child's body weight. Caretakers were asked about health seeking practices with other providers or medications taken throughout the treatment phase of the study.

These reports were validated by the field workers according to the WHO recommended definitions (WHO 1995). Moderate to severely ill children were evaluated by the project physician at no cost to patients and referred to the nearest facilities for further treatment if required.

Sample size estimation

To detect a 5% difference in the likelihood of recovery from ACD by day 7, assuming 85% cure rate and 0.95 level of confidence (one-sided), a power of 0.80, and adjusted by 1.5 for clustering, 925 children were needed per group. To detect a 25% difference in prolonged diarrhoea by day 14, assuming 50% cure rate with a 0.95 level of confidence (one-sided), a power of 0.80, and adjusted by 1.5, 73 cases were needed per group. These estimates were adjusted upward by 10% to account for losses to follow-up. In each ward, there were an estimated 225 children meeting the age requirement. Among these, we anticipated entering 10 new cases per month and that 10% would develop PCD. Based upon six wards per group, a 20-month enrolment period was planned.

Treatment protocol

Standard care

After enrolment, the primary caretaker (parents or other family members) were instructed by a trained, community-based worker (CBW) in the management of their child's illness. The CBWs did not take part in patient care activities. The aims of treatment were correction of dehydration and electrolyte imbalance because of diarrhoeal (salt) losses, maintenance of hydration and the provision of adequate energy intake. Once dehydration was corrected, oral rehydration with WHO recommended, glucose-based oral rehydration solution (ORS) was started but zinc was not provided. If breastfed, mothers were encouraged to continue feeding. After hydration, children were permitted to eat soft foods (rice, boiled fish, potato, bread, egg, milk). Parents were advised to seek health services at their local health facility if their child did not improve.

Green banana-based diet

Caretakers were instructed to procure mature, fresh GB from the market or get it from their neighbourhood garden; fruits were not freely supplied. Whole fruits were cooked in boiling water for 10 min with the skin intact, then cooled and peeled off and the pulp taken out. The amount to be given and the frequency of feeding varied by age of the child. The CBWs were provided with age-adjusted guidelines and trained in their application of GB to children. The quantity was standardized by training mother to measure approximately 100 g of cooked GB (wet wt. of one fruit) using a cheap brand of PVC cup (100 g capacity) available in most households. Most mothers/caregivers (n = 575) were able to measure half or one full cup with mean ± SD weights of 44 ± 9 g and 93 ± 15 g of cooked GB, respectively.

For children aged 6–12 months, the recommended quantity ranged from one-half to one full fruit per day (1/2–1 cup); for 12–24 months, 1–2 fruits (1–2 cups) and for 24–36 months, three fruits (three cups) per day. These

were given as *bharta,* a paste-like suspension in young children or as fried chops or *kebabs (borah)* or just boiled (mash) in older children 3–4 times a day with rice or other foods as they preferred.

Measurements

Children were clinically reassessed by trained field assistants employing a face-to-face interview with mothers for diarrhoeal histories on admission and on days 3 and 7, and if the illness was prolonged, at days 10 and 14.

The day of recovery was documented by the field staff by direct inspection of stool specimen using objective criteria (soft, loose, formed) during the time of the visit and by mothers' report for the two intervening days; the reliability of the reported information was documented earlier (Stanton *et al.* 1987; Luby *et al.* 2009). In addition, mothers were asked to keep tick-marked records in a piece of paper/board or keep counts by using one bamboo stick (six inches) for each loose stool passed by the child; these were rechecked and confirmed by the field staff during their next visit.

Caretakers were also asked to provide information about the source, quantity, quality and cost of the fruits obtained and fed to children. The field staff spot checked the numbers of GB procured and consumed at the time of visit and counted the numbers of empty banana peels stored by the mothers on request for estimating the numbers of fruits consumed during the intervening period. On the day of the visit, the field workers routinely monitored caretakers' concerns related to administration of GB diet.

Data analysis

An intention to treat analysis was carried out. Bivariate and multivariate analyses for the strength of association between group assignment and treatment outcomes were adjusted for clustering using the STATA version 9 cluster survey programme, which accounts for potential within-cluster homogeneity. The primary outcome of interest was the likelihood of recovery from diarrhoea by 7 and 14 days after entry into the study. Cox proportional hazards models were tested to identify adjusted group differences in the recovery rate (hazard ratio) over time (Armitage & Berry 1994).

Results

Figure 1 summarizes the enrolment figures and subject flow throughout the study. Over a 20-month period, 2968 children with an acute episode of diarrhoea were enrolled. All but four parents consented to participate in this study, and 99.9% completed the first week of observation. Among those not treated with GB 198 children continued to have an active illness after 7 days (10.7%), these were entered into the second phase of the surveillance for outcomes of PCD. During the study, three children were lost to follow-up in the standard care group and none in the GB diet group.

Table 1 summarizes the demographic and clinical characteristics of the children at entry into the first phase (ACD) or second phase (PCD) of the study. There were no statistically significant ($P < 0.05$) differences between the

Table 1 Demographic and clinical characteristics of children at the time of admission into the study

	Acute childhood diarrhoea (ACD), *n* = 2968		Prolonged childhood diarrhoea (PCD), *n* = 198	
Characteristics	Green banana (*n* = 1125)	Standard care (*n* = 1843)	Green banana (*n* = 94)	Standard care (*n* = 104)
Age in months (mean ± SD)	18.4 ± 8.8	18.7 ± 8.5	17.5 ± 8.5	16.4 ± 8.9
Males: nos. (%)	622 (55)	941 (51)	51 (54.0)	56 (54)
Females: nos. (%)	503 (45)	902 (49)	43 (46.0)	48 (46)
Body weight, kg (mean ± SD)	8.4 ± 2.8	8.2 ± 2.7	8.0 ± 1.5	7.8 ± 1.6
Body length, cm (mean ± SD)	74.6 ± 28.8	74.9 ± 22.9	73.5 ± 6.8	72.1 ± 6.5
Pre-adm. diarrhea, h (mean ± SD)	29.5 ± 15.0	30.2 ± 15.4	7 days	7 days
Nos. stools past 24 h, (mean ± SD)	6.0 ± 2.2	5.9 ± 2.4	6.0 ± 2.5	6.1 ± 3.0
Vomiting, nos. of children (%)	327 (29)	477 (26)	23 (24)	22 (21)
Bloody stools, nos. of children (%)	76 (7)	85 (5)	3 (3)	3 (6)
WHO ORS (glucose-based oral rehydration solution) given, nos. of children (%)	515 (46)	792 (43)	35 (36)	30 (29)
Drugs given (likely to be antibiotic), nos. of children (%)	81 (7)	167 (9)	9 (9)	6 (6)

ORS, oral rehydration solution.

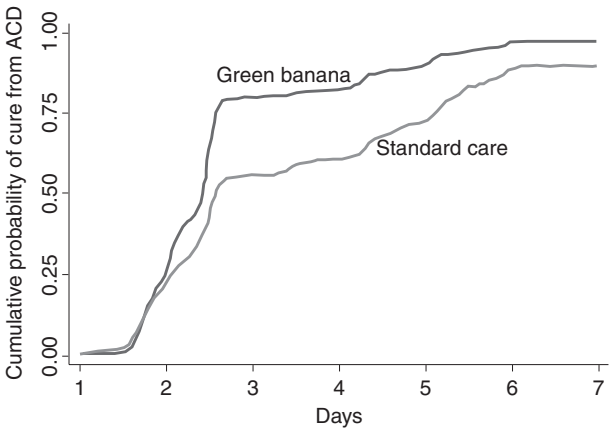

Figure 2 Cox's proportional hazards analysis for recovery from acute childhood diarrhoea.

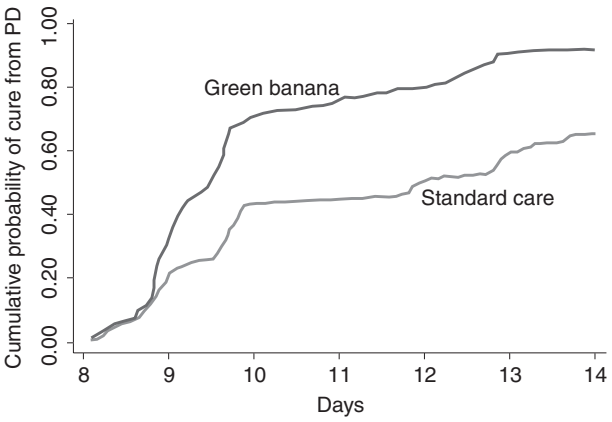

Figure 3 Cox's proportional hazards analysis for recovery from prolonged childhood diarrhoea.

two groups with regard to their clinical characteristics on entry into either the first or the second phase of the study.

Figure 2 presents the cumulative probability (likelihood) of cure from ACD (Cox's proportional hazard), adjusted for host and illness characteristics. A significant difference ($P < 0.001$) in the cumulative probability of cure, favouring the GB group, was found [hazard ratio (HR) = 0.63 (95% CI: 0.56–0.67)]. Children given GB diet were at significantly ($P < 0.01$) lower risk (37%) of continued illness than the comparison group.

Figure 3 presents the results of the same analysis for group differences in the probability of cure from PCD. As with ACD, a significant difference ($P < 0.001$) in the cumulative likelihood of cure from PCD, favouring the green banana group, was found, [HR = 0.38 (95% CI 0.26–0.59)]. There was 27% reduced probability of continued illness in the GB group.

Table 2 describes the bivariate analysis of outcome predictor variables of recovery from acute and prolonged diarrhoea in children. Significant associations of GB, ORS and antibiotics were observed in ACD and PCD; however, antibiotics and stool frequency were not significantly different in prolonged diarrhoea group.

Table 3 summarizes the results of multivariate regression analysis in the model, in addition to main group assignment, that were also predictive of cure from ACD or PCD using logistic regression analysis. Overall, there were 1.64 times (62%) and 2.55 times (72%) increased chances of cure among GB fed children in the ACD and PCD groups, respectively. GB fed children given ORS treatment and having <7 stools/day or having taken an antibiotic had increased chances to recover on day 7 in the ACD group. Among children with PCD, increased chances of recovery by day 14 were associated with having taken an antibiotic. The age of the child and anthropometric status were not predictive of time to recovery.

Table 4 shows the frequency, amount and types of preparations of GB fed to children. In the ACD group,

Table 2 Bivariate analysis of outcome predictor variables of recovery from acute and prolonged diarrhoea in children treated with green banana

Predictor variables	Acute childhood diarrhoea (ACD)				Prolonged childhood diarrhoea (PCD)			
Nos. children	Recovered	Not recovered	Chi square	*P*-value	Recovered	Not recovered	Chi square	*P*-value
GB given	1087	38	52.913	0.0001	85	6	16.934	0.001
GB not given	1643	202			68	31		
WHO glucose-based ORS given	1623	1023	7.186	0.0073	12	50	3.143	0.076
WHO glucose-based ORS not given	450	354			13	21		NS
Antibiotic given*	98	50	9.368	0.0022	6	29	0.044	0.833
Antibiotic not given	656	592			5	20		NS

ORS, oral rehydration solution.
*Drugs likely to be antibiotics.

Table 3 Multivariate analysis (logistic regression) of adjusted covariates as predictors of recovery from acute (ACD) and prolonged (PCD) childhood diarrhoea

	Acute childhood diarrhoea (ACD)			Prolonged childhood diarrhoea (PCD)		
Predictor variables	Odds ratio	95% CI	*P*-value	Odds ratio	95% CI	*P*-value
Green banana (overall)	1.64	1.51–1.78	<0.001	2.55	1.69–3.83	<0.001
WHO glucose-based ORS	1.16	1.08–1.26	<0.001	NS	NS	
Likely to be antibiotic	0.78	0.70–0.87	<0.001	0.49	0.27–0.90	<0.02
Nos. stool >7/day	0.86	0.78–0.96	<0.004	NS	NS	

ORS, oral rehydration solution. NS, not significant.

19–28% of mothers did not feed GB to their children at all and 16–23% mothers did not do so in PCD group, 2–4% children in the standard care group did receive different types of GB as part of their standard treatment (data not shown in table). In the ACD group, most children (77–78%) were given half to less than one full fruit 1–4 times per day, and a small proportion (20–22%) were given 1–2 fruits. Three or more fruits were given to a negligible number of children. In the PCD children, more than 90% were given less than one fruit per day. *Bharta* was the preferred type of preparations given (67–80%), followed by chop *(borah)* and boiled GB. The local cost of a mature fruit was Taka 2–3, thus the daily treatment cost with 2–3 GB per child ranged between Taka 6–9 and for a 5 day course it was Taka 18–27 (US$ 0.026–0.040).

Discussion

The results of this study confirm and further extend our earlier observations that green banana is not only clinically useful in the treatment of diarrhoea in hospitalized children, but it is also effective in the home management of acute and PCD in rural settings (Rabbani *et al.* 2001, 2004). These observations demonstrated that GB can be used as a simple and effective remedy in the dietary management of acute or PCD in the community. For proper implementation of GB-based diet, community motivation and knowledge about the benefits of GB are necessary.

In our study, an effect of GB could be observed as early as 3 days from starting treatment. Whether GB is taken for acute or prolonged diarrhoea, our observations indicate that the optimum therapeutic benefits because of GB occur quickly and are sustained. This finding has important clinical implications since major infective diarrhoeas (cholera, *Escherichia coli*, rotavirus diarrhoea) are usually of rapid onset and short duration (3–5 days) (Rabbani *et al.* 2001). On the 3rd day of follow-up nearly 80% of children receiving GB had recovered from their acute diarrhoeal illness compared to 55% among the comparison children. Children in the comparison groups were at higher risks of developing prolonged diarrhoea compared to GB diet group.

A relatively better effect of GB diet was observed on prolonged diarrhoea, which persisted increasingly throughout the observation period (Figure 3). This finding

Table 4 Frequency, amount, and types of preparations of green banana fed to diarrhoeal children during the period of observations

	Acute childhood diarrhoea (ACD)		Prolonged childhood diarrhoea (PCD)	
Times GB given	Day 3 (*n* = 558)	Day 7 (*n* = 113)	Day 10 (*n* = 40)	Day 14 (*n* = 15)
1–2 times/day	209 (37.4%)	43 (38.0%)	15 (37.5%)	7 (46.6%)
3–4 times/day	329 (58.9%)	66 (58.4%)	20 (50.0%)	7 (46.6%)
>4 times/day	20 (3.6)	4 (3.5%)	5 (12.5%)	1 (6.7%)
Number of GB given/day/child, nos (%)				
<1 fruits	432 (77.4%)	88 (77.9%)	37 (92.5%)	14 (93.4%)
1–2 fruits	124 (22.2%)	23 (20.3%)	3 (7.5)	1 (6.7%)
3+ fruits	2 (0.4%)	2 (1.8%)	0	0
Types of preparation of GB given, nos (%)				
Bharta	379 (67.9)	82 (73.2%)	30 (75.0%)	12 (80.0%)
Chop (borah)	85 (15.2%)	15 (13.4%)	3 (7.5%)	1 (6.7%)
Boiled-mashed	94 (16.8%)	13 (11.6%)	7 (17.5%)	2 (13.3%)

is consistent with our earlier observations that children with persistent diarrhoea had a better response to GB, although the reasons are not clear it may be related to its complex pathogenesis (Rabbani *et al.* 2001, 2004).

The GB effects are unlikely to be aetiology-specific and could be applied to the management of a wide variety of diarrhoeal diseases caused by both non-invasive (secretory) and invasive enteric pathogens (*V. cholera, E. Coli,* rotavirus, and *Shigella* spp.) (Monira *et al.* 2009). This postulation is supported by our recent observations that the GB-based diet given for 5 days significantly reduced the clinical severity (bloody-mucoid stool) and duration of illness in children with severe *Shigella* dysentery (Rabbani *et al.* 2009).

At present, oral rehydration solution (ORS) remains the mainstay of home management of diarrhoea (Rabbani 2000). But ORS alone does not visibly reduce stool volume and its utilization rates still remain at below 30% in many developing countries (Larson *et al.* 2006). Where green bananas are available, they have the potential to be an effective therapeutic adjunct to ORS. Supplementing the green banana diet with other effective antidiarrhoeal agents including zinc as recommended by WHO and Unicef (Bhutta *et al.* 2000) and L-Histidine (Rabbani *et al.* 2005) may increase its therapeutic potential by synergistic actions; these postulations need to be explored by further studies. Fermented milk (Boudraa *et al.* 2001) and complex starch such as hydrolysed guar gum (Alam *et al.* 2005) also showed antidiarrhoeal effects in preliminary trials, which need further evaluation. The mechanisms of antidiarrhoeal action of GB have not been well understood. However, it has been shown that starch present in mature GB fruit is mostly resistant to intestinal hydrolysis and is fermented by colonic microflora into short-chain fatty acids, which stimulate salt and water absorption (Binder 2010). Natural phytochemical compounds (flavonoids, phytosterols, tannins) present in GB may also be responsible for its antidiarrhoeal actions.

There are some methodological issues in our study, which need clarifications. These include the non-blinding of the data collecting staff because of the nature of the intervention under study. However, data collectors sought factual information on illness duration and adherence to treatment guidelines, without precise knowledge of the study hypotheses. Moreover, we relied on mothers' reports for information during the intervening period, this might be less reliable. However, it is a useful method employed in community surveys, and the reliability of the recalled information has been well documented particularly where the recall period is short (2–3 days), as in our study (Stanton *et al.* 1987; Luby *et al.* 2009). Moreover, the possibility of a reporting bias for GB diet may not be excluded despite having good compliance level. The portion size of GB fed to children is very difficult to measure in this study, and our results need to be interpreted within the context of these limitations. Although we were unable to measure energy intake, our surveillance data show that the children came from a homogenous population with comparable dietary intake; likewise energy derived from GB-resistant starch would be insignificant to explain the difference in effect size we observed.

In conclusion, we found that green banana hastened recovery from childhood diarrhoea managed at home in rural Bangladesh. Further research is indicated to better delineate the added value of green banana over current WHO/UNICEF management recommendations that control for energy intake and the use of zinc. Thus, where readily available, the addition of green banana diet to children over 6 months of age holds the potential to be an adjunct to diarrhoea management in children. Further confirmation would be needed before making definite recommendations.

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