3. Clinical studies

3.1 Impact of Lactobacillus (Lactic acid bacteria) in children with acute watery diarrhea

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A total of 148 male children aged between 6 and 24 months suffering from dehydrating acute watery diarrhea of less than 3 days duration were included in this study. After decoding it was observed that 78 children were in study group and 70 were in control group.

Both the groups were comparable with regards to mean value of the following variables: age, body weight, height, MAC, frequency of stools and microbiological findings of stool samples (Table 3.1.1).

After selection, children received two dispersible Lactobacillus tablets (each tablet contains 60 million spores of Lactobacillus sporigen) or placebo tablet two times a day for 5 days even after cessation of diarrhea. Lactobacillus and placebo tablets were identical in colour, shape, size and taste and were prepared in blister strips. Seventy children (89.7%) in study group and 58 (82.8%) in control group recovered within 5 days of hospitalization. Differences of cure rate in two treatment groups was not significant (P=0.222). No significant differences were observed in other outcome variables (duration of diarrhea, mean stool output, ORS intake, plain water + liquid fluid intake) among the children who received Lactobacillus sporigen or placebo (Table 3.1.2); only marginal difference was observed in frequency of stool in two treatment groups (10.81 ± 8.33 in study group vs 14.12 ± 10.26 in control group; p = 0.046)

Table 3.1.1: Characteristics of patients on admission

Characteristics	**Study Group mean ± SD, n = 78**	**Control Group (n = 70)**
Age (month)	12 ± 4	11 ± 4
Body weight (gm)	7861 ± 1441	7491 ± 1488
Height (cm)	70.7 ± 5.7	69.7 ± 6.1
MAC (cm)	13.5 ± 1.1	13.4 ± 1.2
Frequency of stool / day	9 ± 4	11 ± 4
Some dehydration (No, %)	78 (100%)	69 (98.6%)
Enteropathogens (No, %)		
Rotavirus	25 (19.50)	26 (18.20)
Vibrio cholerae O1	2 (1.56)	4 (2.80)
Vibrio cholerae non-O1, non-O139	1 (0.78)	3 (2.10)
Shigella spp.	2 (1.56)	1 (0.70)
EAEC	1 (0.78)	1 (0.70)
ETEC	0	2 (1.40)
EPEC	0	1 (0.70)
Astrovirus	1 (0.78)	0
Cryptosporidium	0	1 (0.70)
E.coli (to be classified)	20 (15.60)	10 (7.00)
Rotavirus + EAEC	3 (2.34)	1 (0.70)
Vibrio cholerae + EAEC	1 (0.78)	0
Vibrio cholerae non-O1, non-O139 + EAEC	1 (0.78)	0
Vibrio cholerae non-O1, non-O139 + Rotavirus	1 (0.78)	1 (0.70)
Shigella spp. + Rotavirus	1 (0.78)	1 (0.70)
Vibrio cholerae + Rotavirus	1 (0.78)	1 (0.70)
No pathogens detected	18 (14.04)	17 (11.90)

Table 3.1.2: Outcome variables

	Study Group (n = 78)	**Control Group (n = 70)**	**p- value**	**Percentage reduction (%)**
No. (%) of patients recovered	70 (89.7)	58 (82.8)	0.222	8%
Mean duration of diarrhea (hrs.)	33.96 ± 20.45	36.51 ± 21.38	0.493	7%
Mean stool output (gms)	742.31 ± 575.41	905.69 ± 622.36	0.126	18%
Frequency of stool (No.)	10.81 ± 8.33	14.12 ± 10.26	0.046	23.4%
ORS intake (ml)	1487.71 ± 675.17	1634.65 ± 783.38	0.257	9%
Liquid + Plain water	5354.42 ± 2652.68	5358.62 ± 2290.06	0.99	0%