Original Article

Efficacy of probiotics as an adjuvant therapy in atopic dermatitis: a randomized clinical trial.

Abu Jafar Md. Shahidul Hoq[1], Fahmida Sultana[2], Zahir Uddin Mohammad Babar[1]

1. Assistant Professor, Dept. of Dermatology and Venereology, Cumilla Medical College Hospital, Cumilla, Bangladesh.
2. Medical Officer (MO), Sheikh Rasel National Gastroliver Institute and Hospital, Dhaka, Bangladesh

Abstract

Background: Atopic dermatitis (AD) is a common chronic inflammatory skin disease in children. Recent studies have suggested that probiotics might have some role in preventing and managing childhood atopic dermatitis.
Objective: To evaluate the efficacy of probiotic in the management of patients with atopic dermatitis.
Materials & Methods: This randomized clinical trial was conducted in the Department of Dermatology of Cumilla Medical College, Cumilla, Bangladesh during February 2015 and February 2016. With informed written consent 120 clinically diagnosed cases of AD were enrolled for the study and divided into 2 groups. Patients of group-I was given topical betamethasone dipropionate and moisturizer and group-II was topical betamethasone dipropionate and oral probiotics. Disease severity was measured by SCORing Atopic Dermatitis SCORAD at the first visit and again at 2nd, 4th and 6th week.
Results: Out of 120 participants' majority were in the age group of 0-5 years. Males outnumbered females in both groups. In group-1, SCORAD index at baseline was 55.25 ± 13.94, at 2nd visit 50.05 ± 14.69 and at 3rd visit was 46.70 ± 14.80. Percent of reduction from 1st visit to 3rd visit was 36.70 ± 8.70. In group-2, SCORAD index at baseline was 49.76 ± 17.25, at 2nd visit 27.39 ± 11.16 and at 3rd visit was 12.08 ± 6.87.The percent reduction of disease before and after treatment was 78.88 ± 8.10.The outcome of two groups at the end of study was statistically significant and better in probiotic group ($p<0.05\%$).
Conclusion: Probiotic is an effective adjuvant in the treatment of atopic dermatitis.
Keywords: Betamethasone dipropionate, Probiotics, Atopic Dermatitis (AD)

Introduction:

Atopic dermatitis (AD) is one of the most common chronic inflammatory skin diseases during childhood.[1-3] The prevalence of this condition has been increasing worldwide over the past few decades due to change in diet and lifestyle.[4,5] Significant physical, psychological and social distress is caused by AD. The disease accounts for 10% to 20% of all referral to dermatologists and about 30% of dermatologic consultations in general practice.[6,7] It is an itchy, chronic, or chronically relapsing, inflammatory skin condition that is characterized by itchy papules which become excoriated and lichenified and typically have a flexural distribution.[1] In 1925, Coca introduced the concept of atopy, meaning "out of place" or "strange", to denote the hereditary tendency to develop allergies to food and inhalant substances.[2] Atopic dermatitis can be classified into three stages: Infantile atopic dermatitis, occurring from 2 months to 2 years of age; childhood atopic dermatitis from 2 to 10 years and adult atopic dermatitis. The cornerstone of treatment and prevention of AD is the moisturizer along with topical and systemic medications. Probiotics are live microorganisms that, when given in sufficient amount confer health benefits on the host.[8] A limited number of studies suggests that probiotics can decrease the severity of AD.

Materials and Methods:

This randomized clinical trial was conducted between February 2015 and February 2016 at the outpatient department of dermatology, Cumilla Medical College, Cumilla, Bangladesh. Inclusion criteria were 0 to 15 years of age; AD that fulfilled the diagnostic criteria by Hannifin and Rajka. A total of 120 patients were enrolled in to the study and informed written consent was obtained from the guardians. They were randomly divided into two

Corresponding author
Dr. Abu Jafar Md. Shahidul Hoq, Assistant Professor, Dept. of Dermatology and Venereology, Cumilla Medical College Hospital, Cumilla, Bangladesh.
E-mail: drshahidulhoq@gmail.com
Received: 05 September 2020 Accepted: 12 November 2020 Available Online: 000
Cite this Article:
Hoq AJMS, Sultana F, Babar ZUM Efficacy of probiotics as an adjuvant therapy in atopic dermatitis: a randomized clinical trial. J. Ban. Acad. of Dermatol. 2021; 1 (1): 10-12

Available at: www.jbadbd.com
An official publication of Bangladesh Academy of Dermatology (B.A.D.)

groups with 60 patients in each. Immuno-compromised and patients with other bacterial skin infections were excluded. Group I patients were given Betamethasone dipropionate 0.05 % topical ointment twice daily for 2 weeks. Group II patients were treated with Betamethasone dipropionate 0.05% ointment twice daily with oral probiotic (Lactobacillus sporegens, Streptococcus faecalis, clostridium butyricum, Bacillus mesentericus) twice daily 2 hours before meal for 2 weeks. SCOring Atopic Dermatitis (SCORAD) was used to evaluate patients on each visit once at the beginning, at 2nd week and 3rd week. All the patients were recalled 6 weeks after the treatment to determine whether they had a relapse. The statistical analysis was carried out with SPSS VER. 20.0 Software and MS-Excel-2016.

Result:

Out of 120 children, maximum children were between the age group of 0-5 years, 53.33% in group I and 58.33% in group II (Figure 1). Male outnumbered female in both groups (Figure 2).

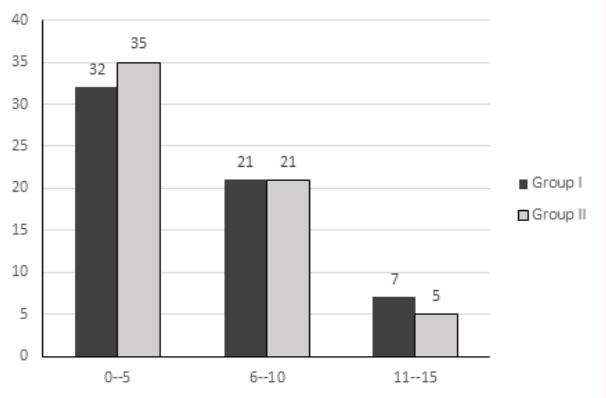
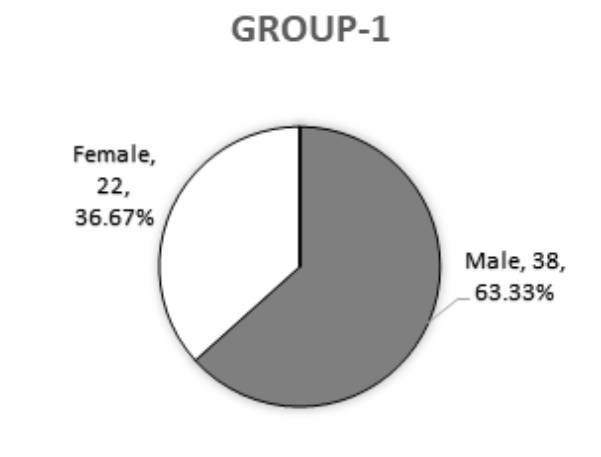


Figure-1: Distribution of participants according to age.



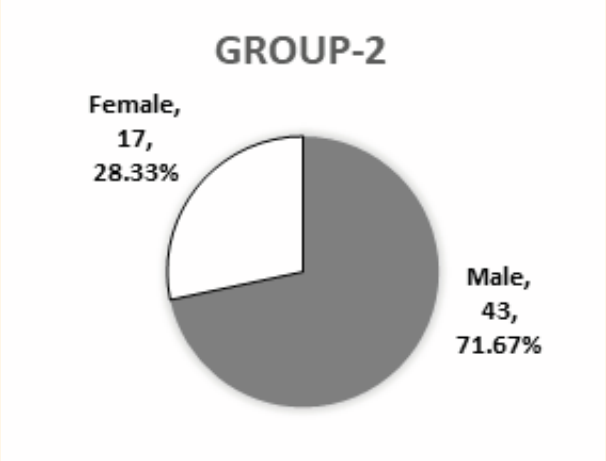


Figure-2: Distribution of the participants according to sex.

Table 1 shows the improvement rate of group-II was better than group-I. In group-1, SCORAD index at the beginning was 55.25 ± 13.94, at 2nd visit 50.05 ± 14.69 and at 3rd visit was 46.70 ± 14.80. Percent of reduction from 1st visit to 3rd visit was 36.70 ± 8.70.In group-2, SCORAD index at beginningwas 49.76 ± 17.25, at 2nd visit 27.39 ± 11.16 and at 3rd visit was 12.08 ± 6.87. Percent of reduction from 1st visit to 3rd visit was 78.88 ± 8.10. To measure p value t test was done and found significant ($p<0.05$).

Table 1: Distribution of patients by SCORAD index (n=60)

SCORAD score assessment	SCORAD score Mean ± SD		*p value
	Group- 1	Group -2	
1st visit (Baseline)	55.25 ± 13.94	49.76 ± 17.25	0.315
2nd visit	50.05 ± 14.69	27.39 ± 11.16	0.001**
3rd visit	46.70 ± 14.80	12.08 ± 6.87	0.001**
Percent of reduction from 1st visit to 3rd visit	36.70 ± 8.10	78.88 ± 8.70	0.001**

*p value obtained from t-test. **p value was significant

Discussion:

Probiotics are useful in balancing gut micro-ecology, restoring intestinal permeability, improving immunological gut barrier function and diminishing pro-inflammatory cytokines production. They selectively stimulate the growth of certain bacteria in the large intestine, improving the bioavailability of calcium, reducing the development of precancerous lesions in the colon and inflammation of the mucosa in various gastrointestinal disorders. Probiotics have been used for centuries and have demonstrated a

very safe profile as they are widely used in premature infants to prevent necrotizing enterocolitis and in immunosuppressed patients and patients undergoing chemotherapy or radiation to prevent and treat diarrhea.[11]

Lee et al. say that there is good evidence for the use of probiotics in prevention but not yet in the treatment of AD.[12]

Pre and postnatal use may reduce up to 61% the development of pediatric atopic dermatitis. A double-blind, randomized clinical trial with 100 children was done by Yang et al. and found no statistical difference between the group who used probiotics and placebo. The study showed that there was intestinal colonization but not a different immune modulation between cases and controls. Research of Pandurur et al.[14] found that probiotics seem to have a protective role in AD prevention if administered in pre and postnatal period in both general and allergic risk population. Administration of probiotics in early life may have a role in the prevention of atopic sensitization, even though it seems to be more effective in severe cases of AD.[14-15]

Another randomized, double-blind, placebo-controlled study investigated the use of L. paracasei (LP), L. fermentum (LF), and LP+LF together in children, and it was observed that the SCORAD scores were lower in the group that received probiotics than those of the placebo group 4 months after discontinuing the probiotic treatment.[16] Comparing children who received L. sakei supplementation to those who received a placebo in a double-blind, placebo-controlled trial, it was found that the supplementation of L. sakei was associated with substantial clinical improvement with concomitant decrease in chemokine levels.[17]

Corticosteroid steroid is the mainstay treatment option of atopic dermatitis but long term use of even topical corticosteroid is associated with both local and systemic adverse effects particularly in children including suppression of hypothalamic–pituitary–adrenal axis. Common cutaneous adverse effects include atrophy, redness, petechiae, striae, hypertrichosis and acne. So they are designed to apply for very short period maximum four weeks. [18]

So adding an adjuvant agent with topical corticosteroid that is already proven may increase its efficacy. Betamethasone dipropionate 0.05% ointment was found effective in the treatment of atopic dermatitis in a study by Vanderploeg, where after three weeks at 3rd visit severity was decreased by 24.9%.[19]

Which is very close to the current study where severity of atopic dermatitis was reduced by 36.70 ± 8.10% with Betamethasone dipropionate. But when probiotic is added with betamethasone dipropionate ointment reduction of disease severity was significantly higher ($p<0.05$). No significant adverse effects were noted.

Limitations of the study:

The current study was not a blinded study and patient bias was present along with observer bias. As a result, the findings may not reflect the real scenario.

Conclusion and recommendations:

Addition of probiotics with topical corticosteroid which is a gold standard therapy for atopic dermatitis can be a novel and effective approach. This study open a new horizon in the management and research in atopic dermatitis.

Conflict of interest

No conflict of interest

References:

1. Oranje AP Evidence-based pharmacological treatment of atopic dermatitis: an expert opinion and new expectations. Indian J Dermatol. 2014; 59(2):140-2. 4.

2. Wang IJ, Wang JY Children with atopic dermatitis show clinical improvement after Lactobacillus exposure. Clin Exp Allergy. 2015; 45(4):779-87. 5.

3. Yang HJ, Min TK, Lee HW et al. Efficacy of probiotic therapy on atopic dermatitis in children: a randomized, double-blind, placebo-controlled trial. Allergy Asthma Immunol Res. 2014; 6(3):208-15.

4. Williams H, Robertson C, Stewart A et al. Worldwide variations in the prevalence of symptoms of atopic eczema in the International Study of Asthma and Allergies in Childhood. J Allergy ClinImmunol 1999; 103:125-38.

5. Medansky RS, Brody NI, Kanof NB et al. Clinical investigations of mometasone furoate: a novel nonfluorinated topical corticosteroid. Semin Dermatol 1987; 6:94-100.

6. Correlae CE, Walker C, Murphy Let al. Atopic Dermatitis: A Review of Diagnosis and Treatment. Am Fam Physician 1999; 60:1191-210.

7. Oh JW, Kim KE, Pyun BY et al. Nationwide study for epidemiological change of atopic dermatitis in school aged children between 1995 and 2000 and kindergarten aged children in 2003 in Korea. Pediatr Allergy Respir Dis 2003; 13:227-37. 3.

8. Hill C., Gauarner F, Reid G, Gibson GR et al. Expert

consensus document: The International Scientific Association or Probiotics and Prebiotics consensus statement on the scope and appropriate use of the term probiotic. Nat. Rev. Gastroenterol. Hepatol.2014;11:506-514.
9. Isolauri E, Arvola T, Sutas E et al. Probiotic may counteract inflammatory response beyond the intestinal milieu. ClinExp Allergy 2000;30:1604-10.
10. Oelschlaeger TA. Mechanisms of probiotic actions - A review. Int J Med Microbiol 2010; 300:57-62.
11. Chapman CM, Gibson GR, Rowland I Health benefits of probiotics: are mixtures more effective than single strains? Eur J Nutr 2011; 50:1-17.
12. Lee J, Seto D, Bielory L Meta-analysis of clinical trials of probiotics for prevention and treatment of pediatric atopic dermatitis. J Allergy ClinImmunol. 2008;121(1):116-21.e11.
13. Kumar S, Mahajan BB, Kamra N. Future perspective of probiotics in dermatology: an old wine in new bottle. Dermatol Online J. 2014 Sep 16;20(9):13030/qt8br333fc. PMID: 25244173.
14. Panduru M, Panduru NM, Sălăvăstru CM et al. Probiotics and primary prevention of atopic dermatitis: a meta-analysis of randomized controlled studies. J EurAcadDermatolVenereol. 2015;29(2):232-42.
15. Michail SK, Stolfi A, Johnson T et al. Efficacy of probiotics in the treatment of pediatric atopic dermatitis: a meta-analysis of randomized controlled trials. Ann Allergy Asthma Immunol. 2008;101(5):508-16.
16. Wang IJ, Wang JY Children with atopic dermatitis show clinical improvement after Lactobacillus exposure. Clin. Exp. Allergy. 2015;45:779–787. 10.1111/cea.12489.
17. Woo SI, Kim JY, Lee YJ et al. Effect of Lactobacillus sakei supplementation in children with atopic eczema-dermatitis syndrome. Ann. Allergy Asthma Immunol. 2010;104:343–348. 10.1016/-j.anai.2010.01.020.
18. Hoare C, Li Wan Po A, Williams H. Systematic review of treatments for atopic eczema. Health Technol Assess 2000; 4: 1–191.
19. Vanderploeg DE. Betamethasone dipropionate ointment in the treatment of psoriasis and atopic dermatitis: a double-blind study. Southern Medical Journal. 1976 Jul;69(7):862-863. DOI: 10.1097/00007611-197607000-00017.