DOI: https://doi.org/10.53350/pjmhs02023171138

ORIGINAL ARTICLE

Effectiveness of Symbiotic in Treatment of Chronic Spontaneous Urticaria: RCT

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ABSTRACT

Background: A challenging health issue nowadays is chronic spontaneous urticaria, which affects almost 2% of the normal population, with half of its sufferers failing to respond to standard treatment therapy.
Aim: To determine the efficacy and safety of a symbiotic in the treatment of chronic spontaneous urticaria.
Method: This was a randomized trial. This experiment at the Lahore General Hospital involved 204 participants with chronic spontaneous urticaria. Participants were randomized into two groups: oral antihistamines plus an oral probiotic sachet (1.5g) twice daily or oral antihistamines alone for eight weeks. The Urticaria Activity Score was used to evaluate efficacy and safety, while the validated Dermatology Life Quality Index assessed quality of life. An independent sample t-test and a Mann-Whitney test were used to compare the age, UAS7, and DLQI score between the two groups. A p-value ≤0.05 was considered significant.
Results: Both treatments significantly improved the UAS7 and DLQI scores from baseline; however, the experimental group produced a significantly greater reduction in the UAS7 and DLQI scores compared to the control group. There was no significant difference in the mean baseline score between both groups. A Wilcoxon signed rank test was used to compare the mean DLQI score before and after treatment in both groups. The results revealed that there was a significant reduction in score from the baseline in both groups.
Practical Implication: Due to a lack of clinical data regarding the effective treatment of this health issue, we planned the current project. The results of this study helped us assess the efficacy of probiotics as adjuvant therapy in our local population and added to our local literature.
Conclusion: It was concluded that the combination of probiotics and antihistamines showed better efficacy than the antihistamine alone, based on the UAS7 and DLQI scores; hence, they can be used as treatment options among patients. Although further research must be done to validate these findings.
Keywords: Efficacy, Safety, Probiotics, DLQI scores, Chronic Urticaria.

INTRODUCTION

A challenging health issue nowadays is chronic spontaneous urticaria, which affects almost 2% of the normal population, with half of its sufferers failing to respond to standard treatment therapy, according to a previous study[1] acute urticarial episode usually lasts for less than 6 weeks, while episodes lasting on most days for more than 6 weeks constitute chronic urticaria as defined by previous literature[2,3]. Unfortunately, pathology, causes, and treatment options are different for both conditions. According to previous studies, acute disease is self-limiting and triggered by the activation of mast cells in response to any allergen. However, other common causes include certain foods containing chemicals, drugs, insect venom, or viral infections[4,5].

On the other hand, chronic disease is complex due to an imbalance among immunity, inflammation, and coagulation processes[6]. Even in this modern era, the pathology of chronic urticaria remains a mystery, although this disease affects the quality of life of its victims badly, so its treatment is a big challenge for health professionals nowadays. Its victims usually present with severe pruritus, dryness, and recurrent wheels that impose mental health issues[7]. This health issue is a very common one, so it requires urgent and effective treatment. Many treatment options were used, but unfortunately, almost 2% of victims showed treatment failure. The most commonly applied treatment is a single antihistamine that showed an almost 30–50% failure rate, as per a previous study[8]. Other treatment options for refractory chronic urticaria include high-H1 antagonists, omalizumab, cyclosporine, or montelukast[9].

Probiotics showed promising results in the treatment of many diseases, like atopic dermatitis (AD), acne, eczema, allergic diseases, and skin aging[10]. Due to the high prevalence of current health issues and their hazardous impact on the quality of life among patients, as well as the partial failure of current treatments, we designed and implemented the following study.

Received on 13-08-2023
Accepted on 07-11-2023

METHODOLOGY

This experiment at the Lahore General Hospital involved 204 participants aged 6–12 with chronic spontaneous urticaria. Participants were randomized into two groups: oral antihistamines plus oral probiotic sachet (1.5g) twice daily or oral antihistamines alone for eight weeks. The Urticaria Activity Score was used to evaluate efficacy and safety, while the validated Dermatology Life Quality Index assessed quality of life. The inclusion criteria included disease duration of over 6 weeks with symptoms occurring at least for 2 days per week, while the duration of each attack lasted less than 24 hours. Those who were unwilling to participate and had any other serious illness like malignancy, thrombocytopenia, or autoimmune disease were excluded.[14-15] All information was collected through questionnaires and recorded on Performa. Written informed consent was obtained at the time of enrollment. Permission was granted by IRB to start this study.
Statistical analysis: The data was analysed using vSPSS-25. Mean ± SD were given for age, UAS7, and DLQI score, while gender was presented by frequency and percentage. An independent sample t-test and a Mann-Whitney t-test were used to compare the age, UAS7, and DLQI score between the two groups. A chi-square test was used to compare the gender distribution between the two groups. A p-value ≤ 0.05 was considered significant.

RESULTS

The mean age of the patients in control group was 38.5 ± 9.2 years and the mean age of the patients in intervention group was 37.2 ± 8.8 as shown by Figure-1.

Table 1 showed that there were 68(66.7%) females in control group and 70(68.6%) females in intervention group.

Table 2 indicated that there was no significant difference in the mean baseline score between both groups. A Wilcoxon signed rank test was used to compare the mean UAS7 score before and after treatment in both groups. The results revealed that there was a significant reduction in score from the baseline in both groups.

However, the Mann-Whitney test revealed that the mean UAS7 score after treatment significantly decreased in the interventional group as compared to the control group.

Figure 1: Comparison of age between both groups

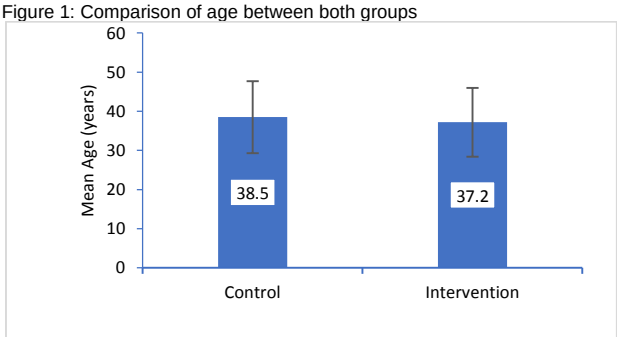


Table 1: Gender distribution of study participants

Group	Male	Female	p-value
Control	34 (33.3%)	68 (66.7%)	0.765
Intervention	32 (31.4%)	70 (68.6%)	

Table-2: Comparison of UAS7 score before and after treatment between both groups

UAS7 Score	Before Treatment	After Treatment	Score Reduction	p-value
Control	33.98±4.74	14.91±2.12	56.1%	< 0.001*
Intervention	33.49±4.88	10.04±1.78	70.0%	< 0.001*

*Statistically significant

Figure 2 showed percentage reduction in UAS7 score before and after treatment in both groups.

Figure-2: Mean reduction in UAS7 score in both groups

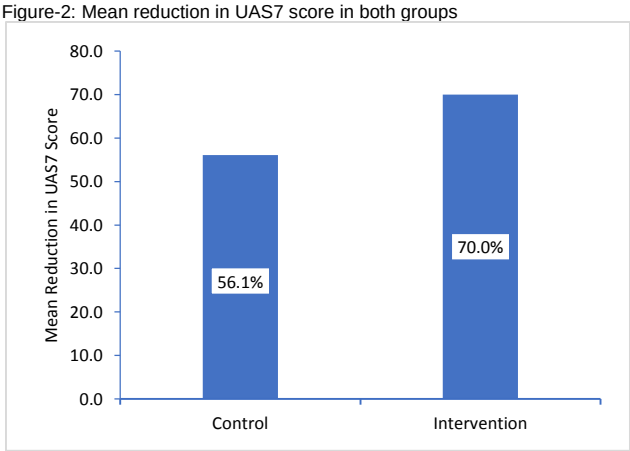


Table 3 indicated that there was no significant difference in the mean baseline score between both groups. A Wilcoxon signed rank test was used to compare the mean DLQI score before and after treatment in both groups. The results revealed that there was a significant reduction in score from the baseline in both groups. However, the Mann-Whitney test revealed that the mean DLQI score after treatment significantly decreased in the interventional group as compared to the control group.

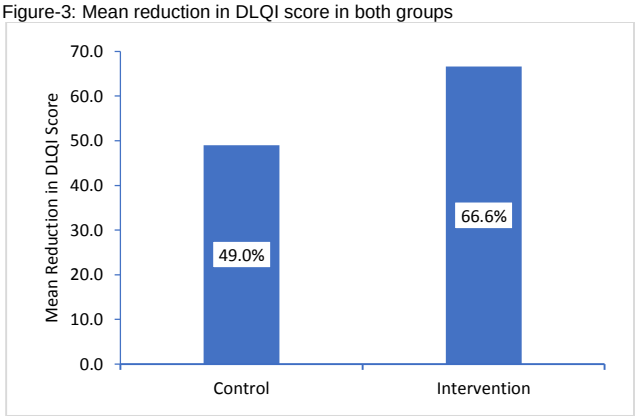
Table 3: Comparison of DLQI scorebefore and after treatment between both groups

DLQI Score	Before Treatment	After Treatment	Score Reduction	p-value
Control	20.43±4.17	10.42±2.31	49.0%	< 0.001*
Intervention	19.89±3.82	6.65±1.18	66.6%	< 0.001*
p-value	0.325	< 0.001*		

*Statistically significant

Figure 3 showed percentage reduction in DLQ1 score before and after treatment in both groups.

Figure-3: Mean reduction in DLQI score in both groups



DISCUSSION

A challenging health issue nowadays is chronic spontaneous urticaria, which affects almost 2% of the normal population, with half of its sufferers failing to respond to standard treatment therapy, according to a previous study[1]. Due to this high treatment failure rate, much research has been done to find an effective medical treatment for this issue with a good response. To the best of our knowledge, the skin is the largest human organ and carries hundreds of microorganisms called the skin microbionta. A literature review showed that these colonised bacteria play a role in immunity by interacting with toll-like receptors on the intestinal epithelial cells and dendritic cells. Thus, their interaction results in the activation of many immune cells, like macrophages, NK cells, and regulatory T cells[12]. By keeping this knowledge in mind, we carried out the current study to evaluate the role of probiotics in chronic urticaria.

The methodology adopted in the current study was in line with one previous study[11] that used a probiotic sachet (1.5g) twice daily with oral antihistamines, but the duration of the study was 4 weeks. Paradoxically, the duration of treatment in the current experiment was 8 weeks. Another study showed a treatment period of 8 weeks[12].

The present study had a sample size of 204 patients, with females (>65%) being in the majority among both groups. Similarly, one study[9,11] had a sample size of 213 patients, while another study[12] had a small sample size of 42 patients. Both studies mentioned above had similar inclusion and exclusion criteria to those used in the present study.

Probiotics are viable microorganisms that possess beneficial effects on the human body when consumed in sufficient quantities and have a proven good safety profile for the host. [10] In the present study, results revealed that there was a significant reduction in score from the baseline in both groups. However, the Mann-Whitney test revealed that the mean UAS7 score after treatment significantly decreased in the interventional group as compared to the control group. Our results were in line with one previous study that showed a significant reduction in the UAS7 score among patients treated with probiotics[12].

In the present study, results revealed that there was a significant reduction in score from the baseline in both groups. However, the Mann-Whitney test revealed that the mean DLQI score after treatment significantly decreased in the interventional group as compared to the control group. Similar results were shown in many previous studies, thus indicating that probiotics in combination with oral antihistamine improve quality of life among victims of chronic urticaria[11,13, 16,17].

Limitations: This current study has a number of limitations, including a single-centre study with limited financial resources. There was a lack of follow-up and genetic workup.

CONCLUSIONS

It was concluded that the combination of probiotics and antihistamines showed better efficacy than the antihistamine alone, based on the UAS7 and DLQI scores; hence, they can be used as treatment options among patients. Although further research must be done to validate these findings.

Author's contribution: MALB: Overall supervision and Write up and literature review.

TL: Statistics application, analysis literature review, help in write up.

Acknowledgement: Thanks to Allah who made it possible.

Conflict of interest: Nothing to declare

Funding: Nil

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This article may be cited as: Bux MAL, Laique T: Effectiveness of Symbiotic in Treatment of Chronic Spontaneous Urticaria: RCT. Pak J Med Health Sci, 2023;17(11): 38-40.