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RESEARCH ARTICLE

BRESOL A NOVEL APPROACH IN ALLERGIC RHINITIS : A CLINICAL STUDY

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ABSTRACT

Allergic rhinitis is a very common disorder that affects people of all ages affects quality of life and productivity at work. Antihistamines, sympathomimetics, xanthine derivatives are commonly used as the treatment for symptomatic management, but they do not prevent recurrent episodes. . Bresol tablets is polyherbal formulations indicated for the management of allergic rhinitis. 100 subjects of either sex aged between 15 to 60 years and suffering from allergic rhinitis like sneezing, nasal congestion, itching of the eyes, itching of the nose, postnasal drip, rhinorrhoea and watery eyes were included in the study. Subjects were advised to consume two Bresol tablets, twice-daily for 6 weeks. All subjects were investigated for evaluated for symptomatic improvement of allergic rhinitis (sneezing, nasal congestion, itching of the eyes, itching of the nose, postnasal drip, rhinorrhea and watery eyes). Subjects were investigated by hematological and biochemical tests at the end of the study period. Bresol tablets significantly reduced the symptoms of allergic rhinitis namely sneezing, nasal congestion, itching of nose, postnasal drip and rhinorrhea and also significantly reduced elevated Total leukocyte count , Erythrocyte sedimentation rate and Absolute eosinophyl count levels without causing clinically significant adverse reactions. Thus it can be concluded that the Bresol tablets are effective and safe in the management of allergic rhinitis.

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INTRODUCTION

Allergic rhinitis is a very common disorder that affects people of all ages, peaking in the teenage years. Allergic rhinitis, often considered a trivial disease, is now increasingly being recognized as a cause of significant and widespread morbidity and affects quality of life and productivity at work. It is the most common allergic disorder, affecting 10-20percent of the population. Allergic rhinitis had been classified as seasonal, perennial oroccupational allergic rhinitis according to the exposed allergens. The condition is characterized by continuous or periodic nasal congestion, rhinorrhea, sneezing, pruritis of the conjunctiva, nasal mucosa and oropharynx, allergic shiners, lacrimation, and fatigue. Poorly controlled symptoms of allergic rhinitis may contribute to sleep loss, secondary daytime fatigue, learning impairment, decreased overall cognitive functioning, decreased long-term productivity and decreased quality of life. Patients with allergic rhinitis typically require multiple medications as no single drug relieves all symptoms of allergic rhinitis. Currently available treatment options for allergic rhinitis have major limitations due to low efficacy, associated adverse events and compliance issues. Antihistamines, sympathomimetics, xanthine derivatives are commonly used as the treatment for symptomatic management, but they do not prevent recurrent episodes. Antihistamines reduce sneezing, itching, and rhinorrhea but not congestion and obstruction. Use of glucocorticosteroids and anticholinergics is questionable due to long term adverse effects. Nasal glucocorticoids (steroids) delivered by a nasal spray are the first-line treatment for the symptoms of allergic rhinitis. These drugs have few side effects and dramatically relieve symptoms in most people. The side effects of nasal steroids are mild and may include a mildly unpleasant smell or taste or drying of the nasal lining. In some people, nasal steroids cause irritation, crusting, and bleeding of the nasal septum.patient has to be compliant while using medication or sprays otherwise the attack of allergy returns. Only immunotherapy with individually targeted allergens has the potential to alter the natural history of allergic rhinitis. Bresol tablets is polyherbal formulations indicated for the management of allergic rhinitis. Bresol tablets contains extracts of Curcuma longa, Ocimum sanctum, Adhatoda vasica, Trikatu, Triphala, Embelia ribes, Cyperus rotundus, Cinnamomum zeylanicum, Elettaria cardamomum, Cinnamomum tamala, and Mesua ferrea.

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MATERIALS AND METHODS

This is a prospective study conducted at department of E.N.T, G.G.S medical college faridkot. 100 subjects reporting to outpatient department of either sex aged between 15 to 60 years and suffering from allergic rhinitis like sneezing, nasal congestion, itching of the eyes, itching of the nose, postnasal drip, rhinorrhoea and watery eyes were included in the study.

Exclusion criteria

Subjects suffering from severe systemic illness, which necessitated use of other medications, were excluded from the study. In all subjects, a thorough ENT examination was done. All subjects were investigated by hematological and biochemical tests, which included Total leukocyte count, Erythrocyte sedimentation rate and Absolute eosinophyl count .Subjects were advised to consume two Bresol tablets, twice-daily for 6 weeks. All subjects were investigated for evaluated for symptomatic improvement of allergic rhinitis (sneezing, nasal congestion, itching of the eyes, itching of the nose, postnasal drip, rhinorrhea and watery eyes). Subjects were investigated by hematological and biochemical tests at the end of the study period.

RESULTS

A total of 100 patients were enrolled in the study. The changes in the values, before the initiation of study and at the end of the study were analyzed by Statistical test: ANOVA test and Paired t test. All values were expressed as Mean ± SEM.p value less than .0001 was considered significant. The mean score of sneezing, nasal congestion, itching of nose, postnasal drip and rhinorrhea decreased significantly at the end of 6 weeks when compared to baseline values.

Table 1.

Symptom	Parameter	Baseline	Week 6
Sneezing	Mean± SE	1.56± .13	.03± .02
	SD	1.3	.3
	p value		<.0001
Nasal congestion	Mean± SE	1.91± .11	.05± .03
	SD	1.1	.2
	p value		<.0001
Itching of nose	Mean± SE	1.01± .10	.03± .01
	SD	1.2	.11
	p value		<.0001
Postnasal drip	Mean± SE	1.75± .10	.04± .01
	SD	.98	.3
	p value		<.0001
Rhinorrhea	Mean± SE	1.79± .09	.04± .02
	SD	.94	.2
	p value		<.0001

There is significant reduction in Reduction in Total leukocyte count Table 2 (Mean=8600±144.4 to 7800±147.5:p<.0001). Erythrocyte sedimentation rate also reduced from Table 3 (Mean=18±1.011 to 11±.665: p<.0001). Significant reduction in absolute eosinophyl count is seen Table 4 (Mean=490 ±19.78 to 210±8.78:p<.0001).

Table 2.

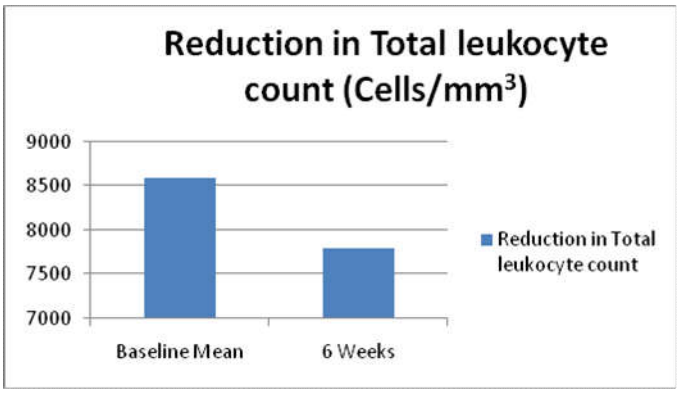


Table 3.

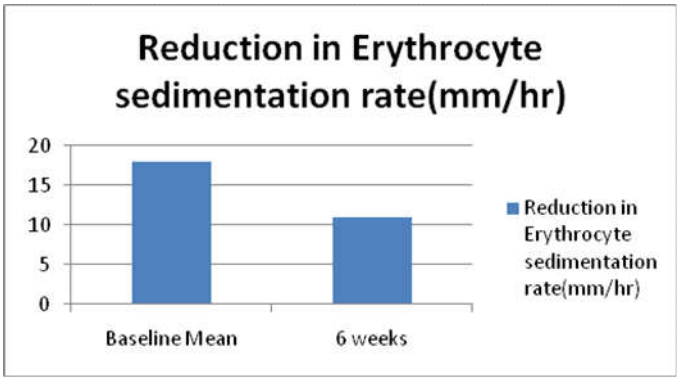
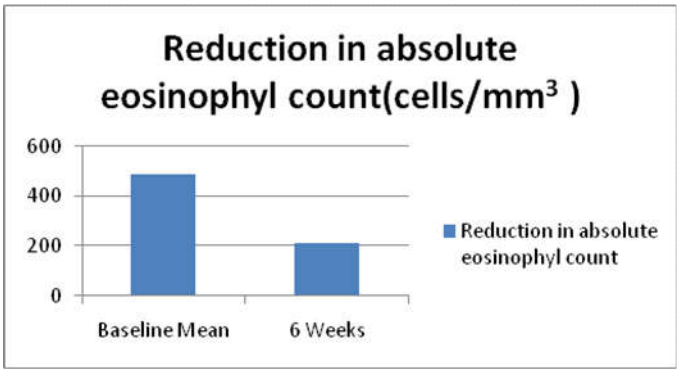


Table 4.



Any adverse reactions were not observed during entire study.

DISCUSSION

Allergic rhinitis is most commonly caused by pollen and mould spores resulting in recurring symptoms throughout the year and the other perennial allergens are house dust mites, feather pillows, animal dander and cockroaches. In this condition, the nasal lining can become inflamed and swollen from the over-response of the body on exposure to various allegens. The major symptoms of Allergic rhinitis are sneezing, rhinorrhea, nasal pruritus and post nasal drip. Sneezing is the most characteristic symptom and activation of the nasal lacrimal reflex leads to the tearing of the eyes. The skin covering the nose and the upper lip becomes tender because of the rhinorrhea and nasal congestion resulting from swollen

turbinates occurs frequently. A characteristic feature is that there is an increased reactivity of the nasal mucosa after repeated exposure to the allergen. Once mast cells are sensitised to specific allergens, re-exposure to the allergen in quantities sufficient to cause cross-linking between allergen and adjacent IgE molecules will lead to degranulation of the mast cell and initiation of various pro-inflammatory events, such as synthesis of interleukins and inflammatory cell infiltration. The effects of mast cell activation may be separated into two separate processes termed the early phase and the late-phase response. The immediate response to allergen exposure is characterized by typical symptoms of allergic rhinitis (i.e., sneezing, rhinorrhea, and nasal congestion) within 5–30 minutes. These initial symptoms are caused by an immediate IgE mediated mast cell response that is followed in 60 –70% of subjects by a late-phase inflammatory response characterized by influx into the nasal mucosa of eosinophils, basophils, and T cells expressing Th2 cytokines including interleukin-4, a switch factor for IgE synthesis, and interleukin -5, an eosinophil growth factor. On re-exposure to antigen, the mast cells degranulate, releasing a number of inflammatory chemomediators like histamine, Leukotriene, Prostaglandin, platelet-activating factor and bradykinin. These chemomediators are responsible for vasodilation, increased vascular permeability, glandular secretion and stimulation of afferent nerves. All these changes culminate in the immediate-type rhinitis symptoms. Overall, the late-phase reaction of allergic rhinitis is characterized by the infiltration of the nasal cavity with basophils, lymphocytes, eosinophils and neutrophils, as well as the release of the same mediators involved in the early response. The characteristic laboratory finding in allergic rhinitis is the presence of large numbers of eosinophils in the nasal secretions. Peripheral blood eosinophilia (4% to 12%) may be present in active allergic rhinitis. A significantly elevated level of serum IgE may occur in the serum of some patients with allergic rhinitis (Ishizaka and Ishizaka, 1976). Nearly 20-30% of patients with allergic rhinitis who have not been treated with specific immunotherapy eventually develop allergic asthma and patients with allergic rhinitis may develop other complications such as recurrent otitis media, impaired speech development, chronic sinusitis, nasal polyps, sleep apnea and aggravation of the existing asthma. Poorly controlled symptoms of allergic rhinitis contribute to sleep loss, secondary daytime fatigue, learning impairment, decreased cognitive functioning and decreased quality of life. The currently available options for the management of allergic rhinitis are avoidance therapy, symptomatic therapy and immunotherapy. Complete avoidance of an allergen results in a cure, when there is only a single allergen, but in most cases of allergic rhinitis, complete avoidance therapy is difficult, because of widely distributed aeroallergens. Antihistamines are useful in controlling some of the symptoms (sneezing, rhinorrhea and pruritus) of allergic rhinitis, but they are less effective in relieving the nasal obstruction and ocular symptoms. Many antihistamines also have anticholinergic side effects like blurred vision, dryness of the mouth, vertigo and central nervous system depression is the major limiting side effect. Mast cell stabilizers have little effect on the mucociliary transport and the adverse effects are frequent (sneezing, nasal stinging, nasal burning, transient headache and an unpleasant aftertaste). Immunotherapy increases the threshold level for symptom appearance after exposure to the aeroallergen and this altered degree of sensitivity may be the result of either the induction of a new antibody, a decrease in allergic antibody, a change in the cellular histamine release phenomenon or interplay of all the three possibilities.

This study observed significant reduction in the mean symptom score for sneezing, nasal congestion, itching of nose, postnasal drip and runny nose (Table 1). The increased levels of Total leukocyte count (Table 2), Erythrocyte sedimentation rate (Table 3) and Absolute eosinophyl count (Table 4) also reduced significantly. These excellent results might be due to the synergistic activities of the ingredients of Bresol tablets .In various studies, curcumins-I, II and III (components of Curcuma longa) have been shown to inhibit chemomediators of inflammation (phospholipase, Lipo-oxygenase, Cyclo-oxygenase-1 and -2, Leukotriene, Prostaglandin, Nitric oxide, collagenase, elastase, hyaluronidase, monocyte chemoattractant protein-1, interferon-inducible protein, Tumour necrosis factor-α, and Interleukin-12 (Chainani, 2003; Hong *et al*., 2002). Inhibition of these inflammatory chemomediators was shown to be due to the ability of curcumins to bind with phosphatidylcholine micelles (Began *et al*., 1998). Curcumins are potent antioxidants. Curcumins also have an immunostimulatory activity, which increases circulating antibody titer, plaque forming cells, alpha-esterase positive cells and phagocytosis (Antony *et al*., 1999). Gingerols and diarylhepatanoids, the principle active ingredients of Zingiber officinale are potent inhibitors of Prostaglandin synthetase enzyme. Cyclo-oxygenase-1 and -2 (regulated by the eukaryotic transcription factor Nuclear factor-kappaB) is the molecular target for the actions of Zingiber officinale, and it acts by interfering with the intracellular signaling cascades, those involving Nuclear factor-kappaB and mitogen-activated Protein kinase (Surh, 2002). Thomson *et al*. documented significant inhibitory effects of Zingiber officinale on Prostaglandin-E2 production (Thomson *et al*., 2002). The principle anti-inflammatory ingredients of Piper longum are dihydrokawain, yangonin and methysticin (Wu *et al*., 2002). Choudhary *et al*. documented that Piper longum inhibits the lipid peroxidation process effectively by its ability to scavenge free radicals involved in initiation and propagation steps (Choudhary and Kale, 2002). The principle ingredients of Emblica officinalis are tannoids (emblicanin A and B, punigluconin, and pedunculagin) (Bhattacharya *et al*., 2000). In addition to the antitussive activity, it was observed that Emblica officinalis has anti-inflammatory, antispasmolytic and antioxidant efficacy and it reduces the mucus secretion in the airways (Sabu and Kuttan, 2002). Terminalia belerica inhibited lipid peroxide formation by scavenging hydroxyl and superoxide radicals in vitro (Godhwani *et al*., 1988). Godhwani *et al*. documented that Ocimum sanctum has an immunostimulatory effect on the humoral immunologic response (an increase in antibody titer), as well as of the Cellular mediated immunity response (E-rosette formation and lymphocytosis) (Singh and Majumdar, 1997). Ocimum sanctum has the capacity to block both the Cyclo-oxygenase and Lipo-oxygenase pathways of arachiodonic acid metabolism (Hanumanthachar Joshi and Milind Parle, 2005). The widely used mucolytics, namely benzylamines (bromhexine and

ambroxol) are the semi-synthetic derivatives of vasicine, extracted from Adhatoda vasica and these benzylamines enhance lysozyme levels in the respiratory-tract secretions and clear bacilli-laden mucus (Chitra *et al*., 2003). Embelin, isolated from Embelia ribe exhibits significant inhibition against five and moderate activity against three stains of 12 bacteria tested (Chitra *et al*., 2003). The aqueous fruit extract of Terminalia chebula has been investigated for its effect on cellmediated and humoral components of the immune system in mice. Piperine isolated from Piper nigrum exhibited prominent nootropic activity (Hanumanthachar Joshi and Milind Parle, 2005). The bark of Cinnamomum zeylanicum strong Free radical scavenging activity and inhibition of hydroxyl radical induced deoxyribose degradation (Dhan Prakash *et al*., 2007).

Conclusion

Allergic rhinitis is a growing health issue with severe impact on quality of life. The available treatment options for allergic rhinitis have major limitations due to fewer efficacies and associated adverse events. This study observed a highly significant reduction in the mean scores for sneezing, nasal congestion, itching of nose, postnasal drip and rhinorrhea (Table 1). The increased levels of Total leukocyte count (Table 2), Erythrocyte sedimentation rate (Table 3) and Absolute eosinophyl count (Table 4) reduced significantly at the end of the study. The significant results might be due to the synergistic activities of the ingredients of Bresol tablets. Bresol tablets significantly reduced the symptoms of allergic rhinitis namely sneezing, nasal congestion, itching of nose, postnasal drip and rhinorrhea and also significantly reduced elevated Total leukocyte count, Erythrocyte sedimentation rate and Absolute eosinophyl count levels without causing clinically significant adverse reactions. The observed effect might be due to the synergistic effect of the ingredients of Bresol tablets. Thus it can be concluded that the Bresol tablets are effective and safe in the management of allergic rhinitis.

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