ORIGINAL ARTICLE

Comparsion of Topical Corticosteroid Nasal Spray / Second Generation Antihistamine with Topical Corticosteroid Nasal Spray

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Author`s Contribution

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ABSTRACT

Objective: To compare the effectiveness of topical nasal corticosteroids alone and in combination with second generation oral antihistamine in the treatment of moderate to severe allergic rhinitis.

Study design: Randomized control trial

Duration of study: One year from 15th June 2011 to 15th June 2012, E.N.T outpatient department Fauji foundation hospital Rawalpindi.

Methodology: 200 cases meeting the inclusion and exclusion criteria were taken from the outpatient E.N.T Department Fauji Foundation Hospital Rawalpindi and informed consent was taken from each of them for using their data in this study. My study variables are age, gender, the effectiveness of treatment given to each of the two groups, rhinorrhoea, sneezing, nasal blocking, nasal itching, post nasal drip and condition of nasal mucosa. Nasal speculum is used to examine the nose with the head light and post nasal drip is seen with the help of tongue depressor. There were 200 patients divided into two groups of 100 patients each. Group I treated with topical nasal corticosteroid spray (flunisolide) and group II receiving second generation oral antihistamine tablet (loratadine) in addition to the topical nasal corticosteroid (flunisolide).

Results: 200 patients were included in the study from E.N.T outpatient department in Fauji foundation hospital Rawalpindi. On the basis of treatments, intranasal corticosteroid spray (INCS) alone and in combination with second generation oral antihistamine patients were divided into two groups of 100 patients in each group and evaluated for effectiveness of each treatment. Effectiveness was assessed by improvement score in symptoms for both the types of treatments to see which treatment of the two was more effective.

Conclusion: The comparative study of Intranasal corticosteroids spray alone and in combination with second-generation antihistamines proved that combination treatment of INCS with antihistamine is better therapy than intranasal corticosteroid spray alone in allergic rhinitis.

Keywords: Allergic rhinitis, Seasonal allergic rhinitis, Perennial allergic rhinitis, corticosteroids, antihistamine.

Introduction

Allergic rhinitis is a symptom complex defined clinically by a combination of two or more nasal symptoms; Rhinorrhoea, Sneezing, Nasal blocking and Nasal itching. It is an altered immunoglobulin E immune response of nasal mucosa to a variety of antigens.[1]

Allergic rhinitis is common and accounts for at least 2.5 % of the entire physician's visit. It is a global health problem with prevalence ranging from 8.8 to 16 %. About 500 million persons worldwide suffer from it. Although not a severe disorder, allergic rhinitis significantly alters patient's social life, affects learning performance at school and work productivity.[2.3.4] The presenting complaints of AR are rhinirrhoea, sneezing, nasal congestion (blocking), nasal itching. The severity of AR is assessed by frequency and intensity of presenting complaints. This is done by assigning numerical values for symptoms, rhinorrhoea, sneezing, nasal congestion and nasal itching (with 0 denoting none, 1 mild, 2 moderate and 3 severe) taking into account subjective intensity and whether these symptoms interfere with sleep, leisure and school or work activities or the duration of symptoms each day (with 0 denoting none, 1 denoting less than 30 minutes, 2 denoting 30 minutes to 2 hours, and 3 denoting more than 2 hours.[1] Allergic rhinitis may be seasonal or perennial depending upon whether the symptoms are present during a particular season or throughout the year respectively. Most allergic rhinitis patients are diagnosed on the basis of history and physical examination. However, Skin prick test, radioallergoabsorbent test (RAST), blood eosinophil count and serum IgE levels are also helpful. At present multiple treatment options exist but topical corticosteroids (INCS) and second generation oral anti histamines form the mainstay of allergic rhinitis treatment.[3,5,6,7]

In practice combination of oral anti histamines and topical corticosteroids therapy is used in moderate and severe cases of allergic rhinitis where there is a poor response to either of these.[3,7] Effectiveness of topical nasal corticosteroids alone and in combination with second generation oral antihistamine in moderate to severe allergic rhinitis was 77%[8] and 90%[9] respectively. This study was conducted because allergic rhinitis is common in Rawalpindi and its surroundings. Study of effectiveness of above-mentioned trial was also lacking. The results of this study will be beneficial in treating ex-servicemen of armed forces and their families in particular and people of this area in general.

Methodology

The study was a randomized control trial which was conducted in outpatient ENT department, Fauji Foundation Hospital, Rawalpindi. The duration of this study was one year spanning from 15th June, 2011 to 15th June 2012. Non-probability convenience sampling was used as a sampling technique. Cases of moderate to severe allergic rhinitis, cases of both seasonal and perennial allergic rhinitis and patients of more than 12 years of age with both genders were included in the study as an inclusion criteria. Pregnant and lactating women, patients with history of epistaxis, nasal injury and previous nasal surgery, patients who used oral antihistamines and decongestants in the past one week, patients who used systemic corticosteroids in past one month, patients on long-term antihistamines and corticosteroid therapy and patients who received immunotherapy were taken as exclusion criteria of the study. Structurally designed performa was used for data collection. Approval of study from ethical committee was taken. 200 cases meeting the inclusion and exclusion criteria was taken from the outpatient E.N.T Department Fauji Foundation Hospital Rawalpindi and informed consent was taken from each of them for using their data in this study. The study variables were age, gender, rhinorrhoea, sneezing, nasal blocking, nasal itching, post nasal drip and condition of the nasal mucosa. Nasal speculum was used to examine the nose with the headlight and post nasal drip is seen with the help of tongue depressor. The sample size was calculated using WHO sample size calculator taking a level of significance 5% and power of test 80%. Anticipated population proportion P1= 77%[8] and P2= 90%.[9] There were 200 patients divided into two groups of 100 patients each. Each patient was selected on the basis of random allocation of patients by lottery method. Group I treated with topical nasal corticosteroid (flunisolide) and group II receiving second-generation antihistamine (loratadine) in addition to the topical nasal corticosteroid (flunisolide). Each patient was followed up on 7th and 14th day to evaluate the effectiveness of the treatment given. Strict record of contact number was kept to ensure follow up. Each patient was observed by myself under the supervision of a consultant. Data was entered and analyzed in SPSS (version 10.0). Mean and standard deviation was calculated for age. Frequency and percentages were presented for categorical variables e.g. gender, the effectiveness of treatment, rhinorrhea, sneezing, nasal blockage, nasal itching, post nasal drip (PND), and condition of the nasal mucosa. Chi-square test was applied for comparative effectiveness in both the groups. P-value less than 0.05 was taken as significance.

Results

Total 200 patients were entered and analyzed in SPSS (version 10.0). Descriptive statistics of age of patients was calculated in each group. For group one treatment patients mean age was 33.31±15.04. For group two treatment patients mean age was 31.98±14.99 as shown in Table. I.

Table I: Descriptive statistics of age in two treatment groups (n=100)

	Two groups	Mean	Std. Deviation
Age (years)	Group A (tarisen nasal spray)	33.31	15.04
	Group B (tarisen + loratadine)	31.98	14.99

Gender wise distribution of patients is shown in Table. No. II. In group one 11 (11%) were males and 89 (89%) were females. In group two 9 (9%) were males and 91 (91%) were females. Low number of males is due to the bias as discussed under pre-treatment workup. After 7 days follow-up of each patient was done and the subjective improvement or no improvement plotted in data collection instrument. This was done for all the patients included in the study. After 7 days effectiveness for each treatment was calculated by chi-square test. P value less than 0.05 was found supporting our hypothesis. P-value of 0.046 after 7 days evaluation was supported by a number of patients who benefited from each treatment. Clearly, a number of patients who benefited from group-2 was greater than patients who benefited from group-1. 76 versus 63. Similarly, each patient was followed up for observation of improvement or no improvement in clinical features after 14 days. It was observed that patients benefiting from group-2 was greater than those who benefited from group-1; 97 versus 85 respectively. The effectiveness of each treatment was calculated by applying chi-square test on the data incorporated in SPSS (version 10.0). The effectiveness of each treatment is shown in Table III.

Table II: Gender wise distribution of patients in each group

		Two groups		
		Group A (tarisen nasal spray)	Group B (tarisen + loratadine)	Total
Gender	Male	11	9	20
		11.0%	9.0%	10.0%
	Female	89	91	180
		89.0%	91.0%	90.0%
Total		100	100	200
		100.0%	100.0%	100.0%

Table III: Effectiveness of each treatment after 07 & 14 days

EFFICACY		Group A (tarisen nasal spray)	Group B (tarisen + loratadine)	p-value*
at 7th day	yes	63 (63.0)	76 (76.0)	0.046
	no	37 (37.0)	24 (24.0)	
at 14th day	yes	85 (85.0)	97 (97.0)	0.003
	no	15 (15.0)	03 (3.0)	
*p≤ 0.05 was taken as level of significance				

P-value was calculated and found to be 0.003 which clearly supports our hypothesis that group-2 was better in effectiveness than group-1.

Discussion

Allergic rhinitis is a global health problem. In recent times, the incidence of allergic diseases has been increasing worldwide.[17] Published data on the prevalence of allergic diseases is lacking in Pakistan. Due to its worldwide prevalence, allergic rhinitis is one of the problems impacting many nations' economy. The management of AR is greatly discussed and variable among the practicing physicians. However, from many options, anti-histamines and topical nasal steroids are the mainstay of the treatment. Anti-histamines alone are effective in mild cases of AR. However, their effectiveness is controversial in moderate to severe AR. They are however having beneficial effects especially second generation anti-histamines like no effect on sedation and early onset of action. [17, 18, 19, 20, 21]

Steroids are effective and are the mainstay of treatment in moderate to severe allergic rhinitis. However, they have a drawback of late onset of action and great many side effects. For this purpose, topical steroids in the form of intra nasal sprays (INCS) and drops are frequently used to avoid their side effects. In our study newly formulated INCS flunisolide (Tarisen) was used alone and in combination with second generation anti-histamines. This was done with the view to gathering the benefits of each of the drug to get maximum relief of symptoms for the patients of allergic rhinitis.[19, 20, 21, 22, 23]

As discussed above in the section of the mechanism of action for anti-histamines and steroids earlier effect and covering of all the symptoms and signs is thus achieved by the combination treatment in group 2. The objective of our study to compare the effectiveness of combined treatment with the effectiveness of INCS alone were delineate clear choice of treatment for the future purposes. In the section of

the review of previous studies on the same topic it was mentioned that certain studies favored equal effect of steroids alone and in combination with second generation anti-histamines. However, studies done on large samples size showed that combination of the two is clearly a better choice. [22- 27]

No side effects of either intra nasal corticosteroids or second-generation antihistamines, like nose bleeding, septal perforation, dryness of mouth or nasal mucosa were reported by any of patients included in our study. Gender bias is mentioned already this might have affected stratification of patients for various age groups and male and female stratification with respect effectiveness but even this did not affect the overall results after completion of the study.

Tsreti Markova and Jhon W Tipton in their study, how effective are nasal steroids combined with non-sedating antihistamines in allergic rhinitis reported that the combination therapy with INCS and second generation non-sedating antihistamines showed no difference in improving the symptoms and quality of life of patients in allergic rhinitis.[19,20,21]

Nelson p and Dahl in their "comparison of INCS and antihistamines in AR, are view of randomized control trials" reported that combining INCS and antihistamines does not provide additional benefits to INCS in patients with moderate to severe allergic rhinitis. [20,21]

Denise K Sur and Stephane Scandale in their article "treatment of allergic rhinitis "in 2010 state that although many studies looked at the combination of INCS and antihistamines but most concluded that this combination therapy was no more effective than INCS alone in patients of Allergic rhinitis.[20,21]

However, in our study results supported our hypothesis in proving that combination therapy of INCS and antihistamine is superior to monotherapy with INCS alone. This is clearly evidenced by the data analysis done in SPSS version 10 which shows p-value of 0.003 after 14 days analysis by applying chi-square test. The overall p-value of 0.003 significantly describes the fact that in our study hypothesis is proven. To support our hypothesis following research work done by different authors is also mentioned. Stempel and colleagues conducted a comparative study on the effectiveness of INCS alone and in combination with second-generation antihistamine. They reviewed 13 randomized control trials and concluded that combination of INCS plus antihistamine was superior to monotherapy with INCS alone in patients with allergic rhinitis. This is in favour of our hypothesis. [23,24]

Camille Andy and colleagues conducted a greater study by involving 16 randomized control trials and concluded that combined therapy of INCS and antihistamine was definitely better than either of these agents alone in terms of effectiveness, early relief of symptoms as well as the quality of life. This also supports the hypothesis in our study.[25,26]. Though Ayubi and colleagues had a drawback of a small sample size of patients but it also proved that INCS with antihistamines is a better therapy than INCS alone in patients of allergic rhinitis. This is another supporting study in proving our hypothesis.[27]

Novaro A and Valero A and their associates conducted a study. Thus, in their original article, clinical use of oral antihistamine and intranasal corticosteroids in patients with allergic rhinitis, reported that combination of INCS and oral antihistamines is the most preferred, effective and widely used option for the treatment of AR irrespective of its type (perineal /seasonal) or severity (moderate to severe). Here again hypothesis in our study is strongly supported.[28] David J Amrol also mentioned the same benefits for the combined treatment of INCS and second generation anti-histamines in his three separate trials on 3398 adolescent's patients of AR thus supporting our hypothesis.[28,29,30] Paul Ratner et al also reported in his study that combination treatment of INCS with antihistamines is a better therapy than INCS alone in patients of AR.[28,29,30]

Conclusion

The results of our study to compare the effectiveness of INCS alone and in combination with second generation oral antihistamines in patients of moderate to severe allergic rhinitis" supported our hypothesis that combination therapy is better than monotherapy with INCS alone in patients with moderate to severe allergic rhinitis after fourteen days of treatment to each group of patients. Epidemiological studies with a large sample size are required to further assess the efficacy of these drugs in our area in particular and at large in general.

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