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Efficacy of Topical Intranasal Steroid Spray in Improving Post-COVID Anosmia at A Tertiary Care Hospital

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ABSTRACT

Objective: Efficacy of topical Fluticasone in improving anosmia in post-COVID patients. **Study Design:** Quasi experimental study. **Settings:** Department of ENT at Combined Military Hospital, Multan Pakistan. **Duration:** Six months from May 2022 to October 2022. **Methods:** patients were divided into two groups of 91 each based on the lottery method. Group A was given topical Fluticasone in 100µg once daily besides olfactory training, while group B only received olfactory training. Patient' smell sensation was assessed by coffee, mint, and garlic. They reported a degree of anosmia on a visual analog scale marked 0 – 10 after 1, 2, and 3 weeks. Data was analyzed using SPSS version 25 for descriptive and comparative statistics. **Results:** 182 patients meeting inclusion criteria were recruited, of which 47.8%were male and 52.2 % were females. The mean age of these patients was 39.23 ± 10.07 years (range; 23 – 63 years), the Mean age in group A was 40.00 ± 9.96 years versus 38.45 ± 10.17 years (P = 0.301) and 152 (83.5%) were aged up to 50 years. Of these 182 patients, (56.0%) were from urban areas, and (71.4%) were from middle-income families. History of diabetes was noted in 29.1%, hypertension in 36.8%, and mean body mass index was 25.21 ± 1.18. Efficacy was 56.6%, in group A and 50.5% in group B (P = 0.101). **Conclusion:** Corticosteroids showed a little higher efficacy, but our study results do not support their use in post-COVID anosmia patients as efficacy was not significantly higher. We suggest that further large-scale studies from different population subsets be conducted to create data-based evidence on this topic.

Keywords: *Corticosteroid nasal spray, Coronavirus disease, Anosmia.*

INTRODUCTION

Otolaryngologists, since the beginning of the worldwide COVID-19 pandemic caused by the *Severe Acute Respiratory Syndrome Coronavirus 2 (SARS – CoV-2)*, have observed a significant rise in olfactory dysfunction in patients affected with this virus.[1] Olfactory illness is a frequent presenting complaint that may appear in approximately 22 – 68 % of infected people with mild disease symptoms. Now, it is widely observed that loss of smell remains a salient feature for COVID–19 infection.[2,3] It has been noted that the clinical course of the olfactory disorder differs greatly among COVID patients, showing recovery rates estimated at 4 % - 89 % reported within 30 days after the start of the loss of smell.[4] Owing to the current perspective of the pandemic and frequent waves of infection in different parts of the world, olfactory dysfunction has become an important concern in the clinical practice of otolaryngology as long-term anosmia may lead to the development of certain behavioral issues like depression and cognitive impairment. For the same reasons, it is an utmost need of the hour to recognize effective management protocols that may improve spontaneous recovery of olfactory functions in affected cases.[5]

Although the majority of cases show recovery during 30 days of onset of impairment, however, it has been shown that approximately half of the cases can persist for their symptoms for 6 months, and one-third can show

symptoms of this impairment after a year.[6] The burden of long-term olfactory impairment differs significantly owing to the variety of methods employed to assess olfactory function and a lack of proper follow-up. Cases presenting with persistent olfactory impairments may also be associated with high-burden depressive symptoms as well as their nutritional status, which negatively affects their quality of life.[7,8] The only treatment strategy for managing olfactory impairments in COVID-19 patients remains olfactory training. During olfactory training, These patients must sniff a set of specific odors every day for 6 months. Olfactory training has been shown to improve the pace and enhance the degree of smell recovery; however, the treatment scope still seems limited.[9]

Moreover, no treatment option shows a clear (i.e., evidence-based) beneficial outcome, although olfactory training is usually helpful in improving olfactory functions in COVID-19 patients. Oral as well as topical corticosteroid agents have been traditionally employed in the treatment of olfactory impairments.[10] However, systemic corticosteroid agents for COVID-19 patients are not indicated as they have the potential for immunosuppression and prolonged duration for viral clearance. Furthermore, the outcomes of topical corticosteroid drugs in patients with olfactory impairment caused by COVID-19 on olfaction recovery still remain to be explored.[11] Hence, this study was designed to ascertain the efficacy of topical corticosteroids nasal spray Fluticasone furoate nasal spray in post-COVID anosmia in our southern Punjab population.

METHODS

A total of 182 COVID patients with post-COVID (PCR confirmed) anosmia of either sex aged more than 18 years were included in this interventional study using a non-probability purposive sampling technique from May 2022 to October 2022. This study was conducted at the Department of ENT at Combined Military Hospital, Multan, after approval of the ethical committee by letter no ERC 17/2022. The sample size was calculated using 62 % efficacy of corticosteroid nasal spray[12] using a 10 % margin of error at a 95 % Confidence interval.

Patients already on nasal steroids, with previous chronic rhino-logical pathologies, on systemic steroids for previous systemic disease, anosmia improved before COVID-19 recovery, Pregnancy, and those who are lost to follow-up were excluded from our study. These patients were divided into groups, Group A and Group B, with 91 patients each based on the lottery method. Group A, having 91 post-COVID anosmia, were given topical corticosteroid nasal spray Fluticasone furoate in an appropriate dose of 2 puffs in each nostril (100 µg once daily) besides olfactory training, while group B, also having 91 patients, did not receive topical corticosteroid nasal spray but only olfactory training. As regards the assessment of smell, all these patients were assessed for their smell sensation employing known materials such as a jar of coffee, a branch of mint, and garlic having specific odors. The patient reported the degree of anosmia on the visual analog scale (VAS) marked 0 – 10 after 1 week, 2 weeks, and 3 weeks.

Data was analyzed using SPSS version 25 for descriptive and comparative statistics. Mean and standard deviation were calculated for age and BMI, while categorical variables like gender, residential status, diabetes, hypertension, obesity, and efficacy. Efficacy in both groups was compared using a chi-square test at a 95 % confidence interval at a 0.05 level of significance.

RESULTS

A total of 182 patients meeting the inclusion criteria of our study were recruited, of which 87 (47.8%) were male, and 95 (52.2 %) were females (in group A, male patients were 48.4 % versus 47.3 % in group B, P = 0.882). The mean age of these patients was 39.23 ± 10.07 years (range; 23 – 63 years), the Mean age in group A was 40.00 ± 9.96 years versus 38.45 ± 10.17 years (P = 0.301), and 152 (83.5%) were aged up to 50 years. Of these 182 study cases, 102 (56.0 %) were from urban areas, and 130 (71.4%) were from middle-income families. History of diabetes was noted in 53 (29.1%), hypertension in 67 (36.8%), and mean body mass index was 25.21 ± 1.18, and 25 (13.7%) were obese. Efficacy was noted to be 103 (56.6%); in group A, efficacy was 62.6% versus 50.5% in group B (P = 0.101).

Table 1: Distribution of efficacy among study cases (n=182)

Efficacy (n=182)	Group A		Group B		P value
	Frequency	%	Frequency	%	
Yes n = 103 (56.6 %)	57	62.6	46	50.0	**0.101**
No n= 79 (43.4 %)	34	37.4	45	49.5	
Total	**91**	**100**	**91**	**100**	

Table 2: Stratification of gender with regards to efficacy in both groups (n = 182)

Gender	Efficacy	Groups		P – value
		Group A	Group B	
Male (n=87)	**Yes** (n=44)	26	18	**0.135**
	No (n=43)	18	25	
Female (n=95)	**Yes** (n=59)	31	28	**0.527**
	No (n=36)	16	20	

Table 3: Stratification of age with regards to efficacy in both groups (n = 182)

Age	Efficacy	Groups		P – value
		Group A	Group B	
Up to 50 Years (n=152)	**Yes** (n=85)	47	38	**0.106**
	No (n=67)	28	39	
More than 50 Years (n=30)	**Yes** (n=18)	10	08	**0.765**
	No (n=12)	06	06	

DISCUSSION

Olfactory dysfunction has a negative impact on the quality of life of the individuals, and these patients have been reported to harbor certain issues with cooking, maintaining their hygiene, public relationships, and various emotional issues such as depressive symptoms. Post-viral olfactory dysfunction remains one of the major causes of loss, and various studies have advocated the role of olfactory training in managing olfactory dysfunction after viral infections.[13,14]

In addition to their role as an anti-inflammatory mechanism of action, various local corticosteroid agents are known to enhance the olfactory functions after modulation of the functions of olfactory receptor neurons by affecting olfactory Na-K-ATPase. Although there is no clear evidence regarding the use of intranasal corticosteroid administration for the management of post-COVID hyposmia or anosmia, these drugs are being prescribed in different settings to improve symptoms and shorten the duration of this dysfunction; hence, this study was conducted to ascertain their effectiveness in COVID patients.[15]

A total of 182 patients meeting the inclusion criteria of our study were recruited, of which 87 (47.8%) were male, and 95 (52.2 %) were females (in group A, male patients were 48.4 % versus 47.3 % in group B, P = 0.882). Abdelalim *et al*. [12] have reported 46 % male patients versus 54 % females in post-COVID anosmia patients, similar to our results. Kasiri *et al*[16] have reported 50 % male patients versus 50 % females in post-COVID anosmia patients, similar to our results. Yildiz *et al*[17] have reported 52 % male patients versus 48 % females in post-COVID anosmia patients, contrary to our results. Rashid *et al*[18] have reported 72 % male patients versus 28 % females in post-COVID anosmia patients, similar to our results.

The mean age of these patients was 39.23 ± 10.07 years (range; 23 – 63 years), the Mean age in group A was 40.00 ± 9.96 years versus 38.45 ± 10.17 years (P = 0.301), and 152 (83.5%) were aged up to 50 years. Abdelalim *et al*[12] have also reported 29 years mean age in post-COVID anosmia patients, similar to our results. Kasiri *et al*[16] have reported a 35.4 ± 9 years mean age of the post-COVID anosmia patients, similar to our results. Yildiz *et al*[17] have reported 37.2 ± 8.4 years mean age in post-COVID anosmia patients, similar to our results. Rashid *et al*[18] have reported 29 years mean age in post-COVID anosmia patients, similar to our results.

Of these 182 study cases, 102 (56.0 %) were from urban areas, and 130 (71.4%) were from middle-income families. History of diabetes was noted in 53 (29.1%), hypertension in 67 (36.8%), and meant body mass index was 25.21 ± 1.18 Kg/m2, and 25 (13.7%) were obese. Abdelalim *et al*[12] have reported 32 % diabetes and 28 % hypertension in post-COVID anosmia patients, similar to our results. Kasiri *et al*[16] have reported a 25.28 ± 4.22 Kg/m2 mean BMI of the post-COVID anosmia patients, similar to our results. Yildiz *et al*. [17] have reported 10 % diabetic patients and 12 % hypertension in post-COVID anosmia patients, contrary to our results.

Efficacy was noted to be 103 (56.6%); in group A, efficacy was 62.6% versus 50.5% in group B (P = 0.101). Abdelalim *et al*[12] reported 62% efficacy in the study group versus 52% efficacy in the control group in post-COVID anosmia patients, similar to our results. However, Kasiri *et al*[16] have reported contrary findings, showing superior efficacy of corticosteroid nasal sprays. Rashid *et al*[18] have reported 82% efficacy in the treatment group versus 84% in the control group in post-COVID anosmia patients, similar to our results. A recent systematic review by Kim *et al*[19] has also concluded that corticosteroid nasal sprays have no significant superior efficacy.

CONCLUSION

Although the use of corticosteroids showed a little higher efficacy, however, our study results do not support the use of corticosteroid nasal spray in post-COVID anosmia patients as efficacy was not significantly higher as compared with the control group.

LIMITATIONS

The study had small sample size. Further large scale studies are recommended to be carried out at other Centre's.

SUGGESTIONS / RECOMMENDATIONS

Owing to the inconsistency in the available literature, it is suggested that further large-scale studies from different population subsets be conducted to create data-based evidence on this topic.

CONFLICT OF INTEREST / DISCLOSURE

None.

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