

Prospective Outcome Assessment of the Importance of Educating Patient Regarding the Use of INCS

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Abstract

Aim: The aim of the study to patient education on nasal spray technique for allergic rhinitis.

Methods: Present interventional study was conducted in the Department of ENT, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India, for the period of 1 year. AR who had never been on steroid nasal spray treatment was included in this study. All patients were treated with intranasal mometasone furoate monohydrate (Nasonex) manufacture by MSD. The dose prescribed was two puffs in each nostril once daily. Each puff contains 50 mcg of Mometasone furoate monohydrate. The patients were reviewed and assessed 4 times after the initial visit. The interval between each visit was 6 weeks.

Results: A total of 100 patients satisfied the inclusion criteria and consented to participate in this study. Patients were between 18 to 60 years old (mean=31.2 years) and among them 38 (38%) were male patients and 62 (62%) were female patients. Based on the 2008 ARIA guidelines, 91 (91%) patients were diagnosed with moderate-severe persistent (MSP) AR, 3 (3%) had moderate-severe intermittent (MSI) AR while 6 (6%) had mild persistent (MP) AR. During the 3rd visit despite re-education, only 27% of participants were able to show the correct techniques. However, by the 3rd and 4th visit, a good improvement was seen as more were able to demonstrate the INCS delivery technique correctly. At the end of the study, all 100 (100%) patients successfully applied and demonstrated proper technique of INCS using the Hospital Putrajaya INCS spray delivery technique. Baseline TNSS on V1 showed that 69 patients (71.9%) came with severe symptoms.

Conclusion: The present study strongly advocates that patient are effectively counseled about proper INCS spray application technique when they receive a nasal spray. Patients must be given clear instructions for correct administration.

Keywords: Nasal Spray, Allergic Rhinitis, INCS Spray.

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Introduction

Rhinitis is inflammation of the membrane lining the nose, characterized by nasal congestion, rhinorrhea, sneezing, itching of the nose and/or post-nasal drainage[1] classified as allergic or non-allergic[2]. Allergic rhinitis (AR) occurs when an allergen is a trigger for the nasal symptoms while non-allergic rhinitis (NAR) occurs when obstruction and rhinorrhea occur. Both allergic and non-allergic rhinitis are highly prevalent and have a significant effect on the quality of life (QOL)[3]. Allergic rhinitis affects about 10–20% of the world population[4]. In Europe and the US, the prevalence of allergic rhinitis was estimated to be 22%[5,6]. Management of AR is important for preventing potential complications. The treatment options include allergen avoidance, pharmacotherapy and immunotherapy. Treatment guidelines support that the use of intranasal corticosteroid sprays (INCS) as the first-line therapy for AR[1,7]. Topical intranasal steroid sprays are highly effective for patients with allergic rhinitis, rhinosinusitis[8,9] and nasal polyposis (NP)[10] and improve the quality of life. They act locally on the nasal mucosa and most available preparations are effective with a once daily dose, which reflects safety, efficacy and convenience[11]. The intranasal steroid sprays have minimal side effects with one common side effect being epistaxis which is usually minor and self-limited which may be the direct effect of corticosteroid, preservative, the pressure of application, or technique used[12]. There exists non-adherence to the self-administered medications due to poor instructions, poor patient-provider relationships and patients' disagreement with need for treatment[13]. Many users use the inhalers incorrectly even after the instructions are provided[14]. The nasal sprays are the drugs for self-medication which become risky when the patients are poorly educated regarding their correct use. Moreover, there is a lack of health professionals who could

provide proper guidance to the user[4]. Because many mistakes are still being made by asthmatic patients during inhalation of lung medication, it is important to gain insight into current techniques used to administer INCS. It may be expected that the administration technique may affect the efficacy, the occurrence of AEs and compliance[15].

Materials and methods:

The present interventional study was conducted in the Department of ENT, Sri Krishna Medical College and Hospital, Muzaffarpur, Bihar, India, for the period of 1 year.

Inclusion criteria:

Inclusion criteria included AR who had never been on steroid nasal spray treatment.

Exclusion criteria:

Exclusion criteria excluded pregnant females, patients with medical co-morbid such as ischemic heart disease, cystic fibrosis and diabetes, and those on antihistaminic/ anti-leukotriene medication, or already on intranasal or systemic steroid were excluded. Patients whom diagnosed to have nasal polyp, nasal septal perforation, granulomatous lesions, nasal masses, or previous nasal surgery were also excluded from the study.

Methodology:

All patients were treated with intranasal mometasone furoate monohydrate (Nasonex) manufacture by MSD. The dose prescribed was two puffs in each nostril once daily. Each puff contains 50 mcg of Mometasone furoate monohydrate. The patients were reviewed and assessed 4 times after the initial visit. The interval between each visit was 6 weeks.

Intervention

Patients were exposed to different methods of teaching on INCS spray technique on each

visit. The 4 different methods of teaching are as mentioned below: Education of technique by pharmacists (E1), education of technique by researcher (E2), education of technique by researcher and providing a pamphlet on the technique (E3) and education of technique by researcher and providing a video showing the technique. The video was sent to patients through email (E4).

E1 method was taught by our hospital pharmacists. The pharmacist techniques are: example of the pictures is as in Figure 1.

Step 1: Shake bottle gently and remove the dust cap. Gently blow your nose.

Step 2: Hold the bottle with opposite hand and point the nozzle outwards, away from the nasal septum.

Step 3: Press once and apply the second puff. Repeat the same technique on the opposite nostrils. E2, E3 and E4 was taught by the researcher.

The nasal spray technique steps that were shown to the patients is as follow:

Step 1: (Figure 1A) gently blow your nose. Remove the dust cap. Hold the nasal spray bottle with thumb at its bottom and the tip in between index finger and middle finger. No need to tilt head forward or backwards.

Step 2: (Figure 1: B, C and D) hold the bottle with left or right hand depending on patient's preference. Insert nasal spray applicator about 30 degree from floor of nostril. Do not tilt the applicator to the side of nostril.

Step 3: Press once and wait for 10-15 seconds before applying the second puff. Repeat the same technique on the opposite nostril.

Pamphlets and video given to patients containing the same instructions along with pictures/audiovisual of the technique. Example of the pictures is as in Figure 1.

Assessment and follow-up

Patients were seen every 6 weeks for 4 times in total after initial visit (V1). On each visit

patients were assessed subjectively using the total nasal symptoms score (TNSS) questionnaire and objectively using active anterior rhinomanometry test.

The TNSS questionnaire consists of nasal symptoms (congestion, rhinorrhea, itching, and sneezing) were scored on a scale (0=none, 1=mild: symptom clearly present but minimal awareness, 2=moderate: definite awareness of symptom which is bothersome but tolerable and 3=severe: symptom is hard to tolerate and causes interference with activities of daily life and sleep). Total nasal symptoms score is 15. Classification of severity according to the total score: very mild (0-2), mild (3-6), moderate (7-9) and severe (>10).

Objective assessment was done using active anterior rhinomanometry test (ATMOS rhinomanometry 300 machine). Active anterior rhinomanometry was performed according to the guidelines of the standardization committee on objective assessment of the nasal airway [16]. Nasal resistance at 150-Pa pressure was taken. Initial visit Rhinomanometry test and TNSS were taken as baseline data. All the Rhinometry test and follow up of patients was done by a single operator.

Flow of the assessment was as described:

Initial visit (V1): Patients completed TNSS questionnaire and baseline rhinomanometry test. After assessment, patient sent to the pharmacy to collect nasal spray and received direct instruction of nasal spray application technique from pharmacist.

Second visit (V2): Patients completed TNSS questionnaire and rhinomanometry test. After assessment patient demonstrated nasal spray application technique using their used nasal spray bottle. Then, researcher taught the patients technique of INCS which has been used by ORL department of hospital Putrajaya.

Third visit (V3): Patients completed TNSS questionnaire and rhinomanometry test. After assessment, patients demonstrated nasal spray

technique using their used nasalspray bottle. Then, patients received education on the hospital Putrajaya INCS spray delivery technique by researcher and pamphlet.

Fourth visit (V4): Patients completed TNSS questionnaire and rhinomanometry test. After assessment, patients demonstrated nasal spray technique using their used nasal spray bottle. Then, patients received education on the hospital Putrajaya INCS spray delivery technique by researcher and a video on the technique was emailed to patients.

Fifth visit (V5): Patients completed TNSS questionnaire and rhinomanometry test. After assessment, patient demonstrated nasal spray technique using their used nasalspray bottle.

Data collection during each visit also included any adverse effect or complications such as epistaxis or septal perforation.

Statistical analysis:

All analysis was performed using statistical package for social science (SPSS) version 23 with statistical significance set at $p < 0.05$. Quantitative data distribution was determined

using the Kolmogorov-Smirnov test. Univariate tests were conducted through descriptive analysis and normality tests. The results are reported in the form of frequency, percentage, mean, and standard deviation, median and interquartile range (IQR). Further analysis using bivariate tests, which were chi-square test (χ^2), Mann Whitney-U, Wilcoxon signed-rank test and Kruskal Wallis test were used to determine whether there was a significant relationship between rhinometry score and TNSS with the different methods of patient education.

Results:

A total of 100 patients satisfied the inclusion criteria and consented to participate in this study. Patients were between 18 to 60 years old (mean=31.2 years) and among them 38 (38%) were male patients and 62 (62%) were female patients. Based on the 2008 ARIA guidelines, 91 (91%) patients were diagnosed with moderate-severe persistent (MSP) AR, 3 (3%) had moderate-severe intermittent (MSI) AR while 6 (6%) had mild persistent (MP) AR [17]. The demographic data and the diagnosing criteria are presented in Table 1

Table 1: Demographic data and diagnosis according to ARIA 2008 classification.

Demographic and diagnostic details		No	Percentage (%)
Age (Years)	≤ 30	54	54
	> 30	46	46
Gender	Male	38	38
	Female	62	62
ARIA	MSP	91	91
	MSI	3	3
	MP	6	6

Abbreviations: ARIA (allergic rhinitis and its impact on asthma), MSP (moderate severe persistent), MSI (moderate severe intermittent), MP (mild persistent), TNSS (total nasal symptom score), V (visit).

Assessment on the techniques during the 2nd (visit 2) showed that none of the participants were able to show a correct technique on the usage of INCS. During the 3rd visit despite re-education, only 27% of participants were able

to show the correct techniques. However, by the 3rd and 4th visit, a good improvement was seen as more were able to demonstrate the INCS delivery technique correctly. At the end of the study, all 100 (100%) patients successfully applied and demonstrated proper technique of INCS using the Hospital Putrajaya INCS spray delivery technique. (Table 2)

Table 2: Improvement of INCS usage technique during each visit after education given to patients.

Visit improvement in technique		No	Percentage (%)
V1	No	-	-
	Yes	-	-
V2	No	100	100
	Yes	0	0
V3	No	73	73
	Yes	27	27
V4	No	15	15
	Yes	85	85
V5	No	0	0
	Yes	100	100

Baseline TNSS on V1 showed that 69 patients (71.9%) came with severe symptoms. These group of patients had not been on any INCS. There was statistically significant association between ARIA classification and severity of

TNSS during V1-V3. Majority of patients with MSP AR had severe TNSS during V1 and subsequently improved to moderate symptoms during V2 and mild/very mild during V3 (Table 3).

Table 3: Association between ARIA classification and severity of TNSS during each visit.

TNSS		ARIA			
		MSP (%)	Others (%)	χ^2	P
TNSS-V1	Mild	7 (7)	6(6)	25.125	<0.001
	Moderate	11 (11)	4 (4)		
	Severe	70 (70)	2 (2)		
	Very Mild	12 (12)	6 (6)		
TNSS-V2	Mild	41 (41)	4 (4)	12.524	0.012
	Moderate	22 (22)	1 (1)		
	Severe	15 (15)	0 (0.0)		
	Very Mild	24 (24)	6 (6)		
TNSS-V3	Mild	39 (39)	2 (2)	7.954	0.044
	Moderate	22 (22)	0 (0.0)		
	Severe	7 (7)	0 (0.0)		
	Very Mild	35 (35)	4 (4)		
TNSS-V4	Mild	42 (42)	5 (5)	1.879	0.51
	Moderate	7 (7)	0 (0.0)		
	Severe	7 (7)	0 (0.0)		
	Very Mild	45 (45)	5 (5)		
TNSS-V5	Mild	34 (34)	6 (6)	1.54	0.825
	Moderate	5 (5)	0 (0.0)		
	Severe	5 (5)	0 (0.0)		

Table 4: Improvement in nasal resistance before and after a different method of nasal spray teaching using rhinometry.

Variables	B-E1	B-E2	B-E3	B-E4	E1-E2	E1-E3	E1-E4	E2-E3	E2-E4	E3-E4
Z	2.889	4.876	6.721	6.655	3.545	5.155	-5.895	-3.280	4.851	-2.279
P	0.002	0.000	0.000	0.000	0.001	0.000	0.000	0.001	0.000	0.023

a. Wilcoxon Signed ranks test, b. Based on positive ranks. Abbreviations: E (education), B (baseline).

Table 5: Improvement in TNSS before and after a different method of nasal spray teaching.

Variables	TNSSE1_B	TNSSE2_B	TNSSE3_B	TNSSE4_B	TNSS E2_E1	TNSS E3_E1	TNSS E4_E1	TNSS E3_E2	TNSS E4_E2	TNSS E4_E3
Z	0.00	0.000	0.000	0.000	0.000	0.000	0.000	0.015	0.000	0.000
P	8.291	8.349	8.464	8.617	5.144	6.185	7.271	2.475	4.978	4.354

Wilcoxon Signed ranks test. Abbreviations: TNSS (total nasal symptoms score), E (education), B (baseline).

The objective assessment of improvement of symptoms and INCS technique after each education method was done using rhinomanometry score. A baseline rhinomanometry was done on V1 and compared between scoring of the other consecutive visits (V2-V4). These Rhinomanometry scoring were done to compare nasal resistance before and after all 4 methods of INCS nasal spray teaching technique. There was statistically significant difference ($p < 0.05$) in nasal resistance when compared with baseline, also before and after each different method of teaching (Table 4) of the other consecutive visits (V2-V4).

The subjective assessment of improvement in nasal symptoms after each method of patient education was done using the TNSS. All the 4

methods of education were compared with baseline and shown to be statistically significant ($p < 0.05$) (Table 5).

Discussion:

Education and monitoring of patient's nasal spray application technique are fundamental elements in the treatment compliance especially for patients with persistent rhinitis. It is important to establish patient's compliance especially when evaluating those who failed to respond to therapy. We have found that patient's symptoms improved by objective test (rhinomanometry) and subjective (TNSS) with each education methods implemented on each visit.

In AR, nasal obstruction is due to the swelling of nasal mucosa especially the middle and inferior turbinate. The inferior turbinate is the main site of swelling. Therefore, the topical steroid must be targeted at this area [18].

Individual nasal anatomy and the method of INCS spray application potentially affect the delivery and distribution of intranasal steroid. Several spray application methods have been described in the various literatures. A number of studies have investigated the intranasal distribution of steroid using an intranasal steroid spray with different application techniques[19]. Some techniques contributed more adverse effects than benefit e.g., epistaxis and septal perforation[20]. Michael et al conducted on a survey of 30 consecutive patients who had been using an INS for longer than 3 consecutive months and who had experienced at least 1 nosebleed in the preceding 2 months[21]. They have concluded that, to prevent epistaxis the recommendation is to point the nozzle outwards, away from the nasal septum[16,20]. None of the studies demonstrated or stressed on how much to tilt the applicator.

On the second visit (V2), after being taught by hospital pharmacist, our observation revealed that patients tend to over point the nozzle laterally from the septum, causing the tip to touch the alar wall, resulting in dripping of the medication from the nose causing discomfort to the patients. This poor administration technique causes reduced efficacy of INCS which leads to persistence of the symptoms. However, as the tip was away from the septum, none of our patients experienced adverse effect such as epistaxis or septal perforation throughout the study.

Beginner and Chong et al. recommended that patient's head is kept in a neutral position when using INCS spray because when the head is tilted back, the intranasal corticosteroid could flow down the throat and cause throat irritation as well as absorption into the gastrointestinal tract[21,22].

Another research, Ganesh et al suggested the contralateral hand technique (for example right hand for left nostril) reduces the adverse effects of INCS spray while increasing patient compliance[19].

Similar method was taught by our hospital pharmacist but there was not much improvement in patients TNSS and Rhinomanometry score.

Another most important issue in treating AR is patient's compliance towards INCS. Compliance has been shown to be poor for INCS use, even in very symptomatic patients. In tropical country, most of the patients have persistent AR and symptomatic throughout the year. They need long-term treatment and ensuring total compliance to treatment can be difficult. The compliance towards INCS improves by educating patient. Effectiveness of topical intranasal steroid may also be limited by lack of patient education on the correct application technique[21]. Many studies focused on finding the correct method of using the nasal spray but none looked at the importance of patient education on the nasal spray technique to help to control AR symptoms. In this study, we have implemented the method of educating the patients with demonstration by the researcher and also by audio-visual technique. With this, we have achieved symptom improvement especially after 2nd visit (V2) onwards and 100% compliance by the end of the study.

In this study, we evaluated the impact of different modes of educating patients on nasal spray application technique through objective and subjective assessment. There is a statistically significant association between rhinomanometry score with severity of TNSS. Majority of the patients with severe TNSS had higher rhinomanometry score compared to patients with mild and moderate symptoms. When the patients were educated on the technique of INCS usage and re-evaluated on each visit, we have noted significant improvement in nasal resistance. Nasal resistance proportional to nasal symptoms, hence improvement in TNSS. The highest increment in rhinomanometry score was seen when comparing education technique E4 (researcher and video) with E1 (pharmacist). This concluded that the

education method on INCS technique by ORL clinic hospital Putrajaya successfully improved the nasal resistance and symptoms of the patients.

In this study, patients slowly learnt to use the ORL hospital Putrajaya INCS spray delivery technique following V2 onwards. By visit 4- (24 weeks), after education of technique by researcher and pamphlet, 80% were able to demonstrate the hospital Putrajaya INCS spray delivery technique. Finally, on the final assessment (V5)-30 weeks, after education of technique by researcher and video, all (100%) patients were able to demonstrate the hospital Putrajaya INCS spray delivery technique.

This study also shows that regardless of age or gender, patients were able to use the INCS correctly after receiving proper patient education. We cannot deny that after INCS prescribed, the regular follow up with assessment of the techniques and repetitive educations of the techniques has impacts on the improvements of the rhinomanometry scores and TNSS. We also observed that patients must be re-instructed regularly on the correct technique of using INCS spray to obtain optimal benefit. Patients showed improvement in signs and symptoms of AR after they were trained on the technique of nasal sprays on every visit by researcher, along with the help of education tools such as pamphlet and video. To date, there are no reports in the literature on educational interventions to teach patients about proper technique of nasal spray application, unlike the education of inhaler technique for asthmatic patients.

Axtell et al emphasized on pharmacists' role is utmost important in achieving a successful asthma treatment as they are the last providers to encounter patients before medication treatment initiated[23]. Study by Basheti et al demonstrated a statistically significant difference when comparing direct pharmacist instruction on proper inhaler technique to having subjects watch a video or read an inhaler pamphlet[24]. They suggest that a brief

2.5-minutes counselling session conducted by a pharmacist can significantly improve a patient's MDI inhaler technique. Pharmacists should spend time explaining and demonstrating proper INCS technique as well as observing patient's technique. Direct instructions and demonstration on techniques shown to be significantly more effective. As revealed by our research, the sign and symptoms, TNSS and rhinomanometry score does not show much of improvement after 1st visit (V1).

Pharmacist and the ORL team of Hospital Putrajaya should implement same education method on INCS usage. With this modification, we can definitely see improvement in signs and symptoms of AR in future. As suggested by Basheti et al pharmacists should spend brief counselling sessions to demonstrate the techniques on 1st visit and re-evaluated by the clinicians on each visit[21].

The aim of this study by giving out pamphlet and video is so that patients can always refer to it whenever needed. There are pros and cons of these education methods. The disadvantage of using pamphlet is that it is easily misplaced by the patients. The video demonstration has advantage of being paperless and patient always can refer to the technique at any time especially those who failed to master even after direct counselling[25]. The best form is probably video as it can be understood even if there is language barrier. Thus, it would be beneficial to the patients by giving out pamphlet and video demonstration where clear instructions were given.

Conclusion:

The present study concluded that the importance of educating patient regarding the use of INCS. We strongly advocate that patient are effectively counseled about proper INCS spray application technique when they receive a nasal spray. Patients must be given clear instructions for correct administration. Therefore, by using our education methods,

especially video demonstration, we are expecting improvement in the treatment of patients with allergic rhinitis. Thus, we strongly recommend on usage of education tools such as video demonstration in near future to combat the disease. Perhaps videos of the INCS spray application technique can be made available in all well-equipped pharmacies and outpatient clinics in the near future.

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