FACTORS AFFECTING CORRECT TECHNIQUE AND COMPLIANCE OF INTRANASAL CORTICOSTEROID SPRAY USAGE IN PATIENTS WITH ALLERGIC RHINITIS

NHRC Provincial Health Research Grant 2079/2080

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Ramshah Path, Kathmandu, Nepal

Submitted by

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2080

Contractual Service Agreement

(CSA)

An agreement made between the Nepal Health Research Council and the Contractor on 20th February, 2023

Dr. Urmila Gurung Principal Investigator (hereafter called Contractor) has been awarded by Nepal Health Research Council (NHRC) for the **Provincial Health Research Grant** of the Fiscal Year 2079/2080 entitled **" Factors affecting correct technique and compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis."** on the terms and conditions mentioned below:

1. **Nature of the service:** The contractor should initiate the research work after the agreement with NHRC and submit final research report latest by June 13, 2023 (30th Jestha 2080).

2. **Duration of the project:** The duration of the study is six months.

3. **Payment schedule:**

   After signing the agreement -50%
   After Submission of Final Report -50%
   The Total amount: Nrs 66150

4. **Deliverables:**
   - Submit two copies of the final report in hard binding copy.
   - Provide the electronic version of the final report.

5. **Income tax:**
   NHRC will deduct tax as per rule of Government of Nepal.

6. In cases where the contractor does not submit the completed project reports within the timeline agreed between the parties, the contractor is obliged to return the whole amount provided by the NHRC. If the solution is not found, NHRC reserves the right to take legal action according to applicable laws of the government of Nepal.

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Member-Secretory (Executive Chief)
NHRC

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Dr. Urmila Gurung
Principal Investigator

IRC approval letter

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079/080

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Ref: **Approval of Research Proposal**

Dear Dr. Gurung

Thank you for the submission of your research proposal, entitled " **Factors affecting correct technique and compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis"**

I am pleased to inform you that after careful evaluation, the above-mentioned research proposal has been approved by Institutional Review Committee (IRC) of Institute of Medicine (IOM), Tribhuvan University on March 16, 2023.

As per our rules and regulations, the investigator has to strictly follow the protocol stipulated in the proposal. Any change in title, objectives, problem statement, research questions or hypothesis, methodology, implementation procedures, data management and budget may be made so and implemented only after prior approval from IRC. Thus, it is compulsory to submit the details of such changes intended with justifications prior to actual change in the protocol.

Please note that you can start recruiting the research participants only after getting approval letter from the IRC. You are also requested to follow the ethical guidelines of IRC of IOM.

After completion of your study, you must submit a copy of final draft of your research to the Research Department.

If you have any further queries, please do not hesitate to contact us.

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Preface

Sustainable Development Goal 3 (SDG3) promotes good health and well-being. Maintaining a good quality of life also equates to good health and well-being. Non-communicable diseases pose a huge burden on the health care system. Addressing these diseases at prevention level has the most desirable outcome but this may not always be practical. So, for those who already have developed the disease, the next step forward would be to minimize the effect it has on the quality of life by use of medications. Complying to medication has direct effect on the outcome of the medication use.

The same applies for allergic rhinitis management. Complying to usage of nasal sprays not only alleviates the relevant symptoms but also avoid further progression of other allergic manifestations like bronchial asthma, allergic rhinoconjunctivitis. Keeping the symptoms under control would mean promoting well-being and subsequently a healthy life which the SDG3 advocates.

Unfortunately, there is a paucity of research evaluating any setbacks and underlying causes associated with non-adherence to the INCS. As a result, this research was conducted with an aim to provide a better understanding of the existing situation and help determine steps to increase compliance and ensure proper nasal spray technique. This research was funded by NHRC under the “Provincial Health Research Grant 2079/2080.

Acknowledgements

I would like to thank Dr Sajish Khadgi, lecturer and all the residents from the Dept. of ENT-Head and Neck Surgery, Maharajgunj Medical Campus, Institute of Medicine, Kathmandu for their help while conducting the research. I would also like to thank Mr Bibek Bhattarai for his help during manuscript writing. Last but not the least, I would like to thank all the patients for their participation in this research.

ABSTRACT

Objective: To identify factors affecting correct technique and compliance of intranasal corticosteroid (INCS) spray usage in patients with allergic rhinitis.

Methods: It was a cross-sectional study conducted in the Dept of ENT-Head and Neck surgery, Tribhuvan University Teaching Hospital from April to September 2023. Patients aged 18 or more with allergic rhinitis on INCS or used INCS in the past three months were assessed for INCS administration technique based on EPOS 2020 protocol and their compliance asked. Factors that could hinder the correct techniques and compliance were assessed.

Results: A total of 138 patients, 71 males and 67 females, aged 18 to 72 years were included. Most of them (60/138; 43.5%) had completed secondary level education. 97.1% (134/138) had been prescribed INCS spray by an ENT doctor and 89.13% (124/ 138) patients had received verbal instructions mostly by ENT doctor (91.1%). 7.2% (10/138) patients completed all the steps of INCS administration technique as per EPOS 2020 protocol whilst 25/138 (18.1%) completed five essential steps. The correctness of the INCS administration technique however did not differ with age, gender, academic qualification, prescriber or whether instructions were given or not. Compliance was seen in 119/138 (86.2%). Amongst the 19 (13.7%) non-compliant patients, improvement in nasal symptoms in 13, no symptom improvement in two, cost factor in two and side effects like nasal irritation in two were observed. These factors were statistically different between compliant and non-compliant patients. The correctness of the technique did not affect the compliance.

Conclusion. INCS spray was scarcely administered in the correct technique however the compliance was good. There were no identifiable factors associated with correctness of the INCS spray technique however, the compliance depended on the cost, side effect to INCS. As for symptoms, both improvement or no improvement could deter compliance.

Keywords: Intranasal corticosteroid, allergic rhinitis, compliance, spray technique

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AR	Allergic rhinitis
HRQOL	Health related quality of life
INCS	Intranasal corticosteroid
ARIA	Allergic Rhinitis and Impact on Asthma
EPOS 2020	European Position Paper on Rhinosinusitis and Nasal Polyps 2020
WHO	World Health Organization
IQR	Interquartile range

Chapter 1: Introduction

1.1 Introduction

Allergic rhinitis (AR) is a worldwide health problem affecting over 500 million people globally.[1] Not only does it impairs the health related quality of life (HRQOL) but also has a huge economic burden.[2] An estimated annual cost of allergic rhinitis ranges from US$2 billion to 5 billion with work absenteeism and lost productivity accounting for substantial indirect expense.[1] Hence, addressing allergic rhinitis is of utmost importance to regain a good quality of life, productivity and subsequently prevent indirect expense.

Intranasal corticosteroids (INCS) is the standard first line therapy for treatment of AR.[2] It controls symptoms without much systemic side effects when sufficient drug concentration reaches the nasal mucosa.[2]. It may, however, take several weeks before optimum symptom control can be achieved.[2] Thus, regular application using correct technique of INCS is of utmost importance in keeping AR under control.

Regular INCS usage using correct technique is a challenge while managing AR.[3,4,5] Non-compliance rate accounts for around 30% in AR patients needing INCS.[6,7] Poor symptom control or symptom improvement, adverse effects, and concern over the negative consequences of steroids can reduce compliance with INCS.[3,4,7] Side effects like nasal irritation, dryness, epistaxis, headache and rarely septal perforation are known to occur with INCS.[2] Poor clinical outcome and side effects are associated with incorrect spray technique.[6] In a study by KC et al.[8] more than 90% patients on INCS demonstrated poor nasal spray technique.[8] Similarly, Waqas et al.[6] also had only 1 out of 99 patients using steroid nose spray in a completely correct manner. So, incorrect application of nasal spray is quite common.

Current guidance on the management of allergic rhinitis strongly recommends clinicians to check nasal spray technique and compliance.[6,9] However, instructions to patients are skipped as indicated by two studies done in developed countries where only 40-53.5 % of patients were given instructions for nasal spray application technique. [6,7]

The scenario in Nepalese context could be more similar or worse as patient education is often not given priority due to limitation of time and resources.

There are patient instruction materials for nasal sprays available in several English medical websites. [6,8] In our context, manufacture instructions are available with the nasal sprays but they may be difficult to understand as they are not available in the native language [8] which may further hinder proper usage of the nasal sprays.
Disparity between the ideal INCS spray usage as opposed to what the patient ultimately does is apparent but the gravity of the situation and the underlying factors are still unexplored. So, this study will find the factors that influence the correct technique and compliance to INCS and also give an insight on the prevalence of inappropriate nasal spray technique. This would ultimately form a basis to develop strategies to overcome these barriers. Patients complying to medications will result in symptom control hence an improvement in HRQOL and subsequently higher productivity and reduction in economic burden.

1.2 Rationale/ potential impact of the project

Patient education has not been given its due importance in our healthcare system. Understanding how patients are self-administering the frequently used drugs is crucial given the widespread usage of INCS and the goal to attain ideal angles for drug deposition.[9]

There may be considerable number of AR patients who may not have been given the right instruction or information about the nasal sprays which could have resulted in decreased compliance. Analyzing the difficulties or deterrents faced by the patients as seen from their perspective is crucial in developing measures so the patients follow what exactly needs to be done.

Non communicable disease like allergic rhinitis although not life threatening but can be very morbid. This can cause poor quality of life and subsequently result in socio-economic burden for both the patient and ultimately to the nation if many patients end up being affected. So, it is important to assess what the current scenario is with regards

to correct technique and compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis as research on this subject is scarce.

Unfortunately, there is lack of literature assessing any setback and underlying reasons related to non-compliance of prescribed INCS in our context. This research aims to address this void. The result of this study provides an idea of the current scenario which will further guide as to what measures need to be taken to improve the compliance and proper nasal spray technique. This will emphasize on the need for patient education and the methods to facilitate patient education. Once the effective methods for patient education are identified based on the needs from patients' perspective, they can be incorporated on a national level health policy for a wider reach.

1.3 Literature review

1.3.1 Allergic rhinitis and its burden

Allergic rhinitis is widely prevalent, with over 500 million people being affected worldwide. It presents mainly with four cardinal symptoms namely sneezing, rhinorrhoea, nasal congestion and itching alongside other symptoms like itching of the eyes, palate, lacrimation and conjunctival irritation. If left untreated, the susceptibility for more serious respiratory diseases increases.[10]. This could cause sleep disturbance, impact on many aspects of cognitive function and affect, work absenteeism and loss of productivity.[1] As a result, the overall health related of qualify of life is impaired.

Although a huge contributor of work absenteeism and lost productivity, public awareness about the morbidity associated with allergic rhinitis has not been given its due importance as for other chronic illnesses like hypertension and diabetes. This probably could be the reason for only 13% allergic rhinitis patients seeking treatment in the United States.[11] However, it is associated with a huge economic burden as the cost associated with allergic rhinitis could be both direct, related medical treatment and indirect, related to non-medical losses. [1,2] Hence it needs to be addressed with utmost importance.

1.3.2 INCS for treatment of allergic rhinitis

The Allergic Rhinitis and Impact on Asthma (ARIA)Workshop report recommends INCS as the first-line treatment of choice for management of allergic rhinitis as a part of pharmacotherapy, alongside environmental control measure and allergen immunotherapy when indicated. [11]

Steroids are potent anti-inflammatory agents which are effective in preventing and relieving allergic nasal symptoms hence can play significant role in improving the health-related quality of life in allergic rhinitis patient.[2] However, systemic side effects mainly suppression of the hypothalamic-pituitary-adrenal axis and growth, osteoporosis, and cataract formation are a major concern in oral form.[10] Fortunately, they are available in topical form also, one of them being INCS spray. INCS block the early phase of the allergic response by reducing IgE-mediated mast cell activation and associated cytokine release. The late-phase response is reduced by their effect on the T lymphocytes, eosinophils, basophils, and neutrophils. [10]

The INCS spray deposits the steroid directly on the nasal mucosa which offers a large area and easy access to the medication.[10] Hence, it facilitates adequate concentration of steroid to reach the receptor site on the nasal mucosa so it can act locally to decrease inflammation. [2,7] This allows for prolonged, continued use.[7] Most INCS are safe for both adults and children at recommended dose with little concern related to systemic side effects secondary to drug absorption via nasal mucosa or in the gastrointestinal tract when some INCS gets swallowed. [2] Its usage can have significant good short term and long term clinical outcomes.[12]

However, INCS requires at least a few days for some clinical improvement to be experienced and may take several weeks for total response, so it cannot be used ad hoc but needs application on a regular basis.[2] Since, allergic rhinitis is a chronic disease, INCS has to be used long term for it to remain optimally effective. Not only does the patient need to be compliant for regular usage, it also has to be administered ensuing a proper, precise technique.

Although considered effective for allergic rhinitis, in clinical practice, its efficacy is found to be relatively less than reported in randomized controlled trial. This probably could be a result of differences in patient's compliance.[11]

1.3.3 INCS and compliance

A meta-analysis on health literacy and adherence to medical treatment in both chronic and acute illness showed health literacy interventions affected adherence.[13] Health literacy is patient's ability to have access and understanding of basic health information to make the best possible health decision. When patients are well informed and clearly understand their role in the management, they are more likely to adhere to regimens recommended to them.[13]

Non-adherence to self-administered medications like INCS could result from improper instructions, poor relationship between the patient and the service provider, patient unconvinced about the need of medication. Similar scenario is shared by asthmatic on inhalers. Improper administration technique can result not only in reduced efficacy but also can cause adverse effects hence reducing compliance.[8]

Other aspects of non-compliance of INCS users as noted by Ocak et al.[14] are persistence of symptoms inspite of taking INCS, side effects to INCS, lower education status and also time constraints for self-care due to family obligations if more than two dependent children.

In a study by Ganesh et al.[7] the non-compliance rate of INCS was 29.1% (30/130). Non-compliance resulted mostly due to nasal irritation (13), no symptom improvement (7) and epistaxis (6) hence indicating lack of symptom resolution and side effects as contributory factors.

Loh et. al[11] assessed the compliance to INCS in allergic rhinitis patients. Amongst the 63 patients, 49 (77.8%) patients admitted to forgetting using the medication. Thirty days after rigorous patient education on proper INCS administration, a fairly sizeable number (11%) of patients did not administer even 50% of the treatment dose. So, they noted that compliance decreased with time due to chronicity of this condition. Hence

Ocak et al.[14] stressed on assessing the patient on regular interval, re-evaluate the medication and re-emphasize to take the prescribed medicine to promote compliance.

1.3.4 Side effects of INCS

Most INCS especially the newer compounds like fluticasone proprionate, triamcinalone acetonide, mometasone furoate, budesonide, flunisolide, and beclomethasone proprionate are safe for both adults and children at recommended dose.[10] They get metabolized in the liver rapidly even if absorbed systematically via nasal mucosa or the gastrointestinal tract when swallowed hence has negligible systemic side effects.[2]

Local nasal side effects like dryness, burning and stinging, and sneezing, together with headache and epistaxis have been reported in 5–10% of patients with epistaxis and nasal irritation being common. [2, 7, 15] These are usually self-limiting.[10] Septal perforations are rare.[2] INCS is assumed to cause local side effects by mechanical and chemical trauma which can escalate when using the ipsilateral hand technique where the INCS is likely to be directed towards the more sensitive and vascular septal mucosa. [7]

A survey by Ganesh et al.[7]amongst patients using intranasal steroid sprays evaluating the spray technique used, side effects and compliance showed 22 out of 103 patients (21.4 %) reported side effects, including nasal irritation and epistaxis. Amongst the 20 patients who had epistaxis, 80% used ipsilateral hand technique. 77 % of the 30 patients who had poor compliance secondary to side effects or no improvement in symptom also used ipsilateral hand technique. Since patients using ipsilateral hand to apply INCS were more likely to develop epistaxis and have poor compliance, it was suggested to be avoid this technique.[7] The side effects and the subsequent reduced compliance were mostly attributed to faulty INCS administration technique. Rattanawong et. al[15] also noted the risk of epistaxis and nasal irritation increasing by 3.6 fold if pointing the nasal spray towards the septum. Faulty head up position leading to side effects and poor symptom control is also considered an important factor relating to patient's non-compliance.[7] Thus, standardizing the INCS application technique helps both patient and healthcare provider to follow the same technique which facilitates proper steroid distribution and maximum effectiveness.[10]

1.3.5 INCS spray administration techniques

There is a lack of standard guideline for INCS administration in the literature as pointed out by Benninger et al.[10] Hence, different protocols have been utilized to assess the correctness of the techniques.

Following an exhaustive literature review, European Position Paper on Rhinosinusitis and Nasal Polyps 2020 (EPOS 2020) [10] has proposed the technique for correct INCS administration. The technique involves 13 steps which comprises of steps related to preparation before spray administration to procedures needed to be followed after spray administration (Table 1).

Table 1. EPOS 2020 INCS administration technique

Steps		
Before spray administration	1.	Gently blow the nose
	2.	Shake the spray bottle vigorously
	3.	Remove the cap
Head position	4.	Keep your head upright
Spray tip direction	5.	Gently insert the nozzle tip into one nostril
	6.	Aim the tip of the nozzle away from the septum
	7.	Use right hand to spray the left nostril and vice versa
Free nostril	8.	Do not close the nostril not receiving the medication
Spray administration and breathing pattern during spray administration	9.	While slowly breathing in, press the nasal spray
	10.	Apply the number of spray recommended
After spray administration	11.	Take the nozzle out and breathe out through your mouth
	12.	Repeat the administration step in the other nostril
	13.	Clean the spray nozzle and replace the cap

Benninger et al.[10] pointed out the lack of a "gold standard" test for the effective INCS spray technique which made it difficult to assess the data in various studies. Based on review of 34 articles related to the spray technique, they proposed seven essential steps (Table 2).

Table 2. Proposed essential steps by Benninger et al.

	Steps
1.	Hold head in a neutral upright position
2.	Clear nose of any thick or excessive mucus, if present, by gently blowing the nose.
3.	Insert spray nozzle into the nostril.
4.	Direct the spray laterally or to the side, away from the middle of the nose (septum) and toward the outer portion of the eye or the top of the ear on that side. (If possible, use the right hand to spray the left nostril and left hand to spray the right nostril, to direct the spray away from the septum.)
5.	Activate the device as recommended by the manufacturer and with the number of sprays recommended by the doctor.
6.	Gently breathe in or sniff during the spraying.
7.	Breathe out through the nose.

A prospective pre- and post-interventional study was conducted by KC et al. [8] to evaluate the nasal spray use technique using the standardized 11 step World Health Organization (WHO) nasal spray checklist (Table 3). Patients were asked to demonstrate the technique and were scored as per the checklist. This was followed by individualized education and training on the correct use of nasal spray by a registered pharmacist with the help of a pictorial leaflet in the local language. Their nasal spray technique was re-evaluated after 10 days.

Table 3. WHO check list.

Steps	
1.	Blow the nose
2.	Sit with head slightly tilted forward
3.	Shake the spray
4.	Insert the to tip into the nostril
5.	Close the nostril and mouth
6.	Spray by squeezing the vial and sniff slowly
7.	Remove the tip from the nose and bend the head forward strongly (head between the knees)
8.	Sit up after few seconds
9.	Breathe through the mouth
10.	Repeat the procedure for other nostril if necessary
11.	Clean the tip

Amongst the 81 patients included in this study, less than 10% patients correctly demonstrated all the given steps. Amongst age, gender, marital status, education and occupation, only education was found to be significantly associated with the correct spray technique.

Further breaking down the steps, shaking the spray and inhaling while spraying was mostly performed (90.10% and 85.2%, respectively). Seventy-nine (69%) patients inserted the tip of the spray correctly, i.e., aiming laterally whilst only 19 (23.50%) blew their nose. None of them followed Step 7 (bending the head between the knees immediately after application) and Step 8 (sitting up after a few seconds). These two steps are unique to WHO checklist only and not mentioned in other protocols. Hence, they are most often omitted so it is obvious to find these two steps not being followed. Only nine (11.1%) breathe out through the mouth. A mere 3.70% patients cleaned the tip after use indicating the lack of awareness of the tip cleanliness. The poor nasal spray technique could be due to inadequate instruction during medicine dispensing or patient forgetting the correct steps. Following the pharmacist-led intervention on nasal spray use technique, there was substantial improvement in demonstrating the correct INCS

administration technique by 84% patients. The study thus recommended the need for regular assessment and reinforcement of the correct technique by health worker.

Similarly, Rattanawong et al.[15] based their assessment on 12-steps technique for the accuracy of INCS administration. These steps were adapted from previous studies. Amongst them, five steps were selected as the recommended steps (Table 4). 150 patients with allergic rhinitis were included in this study. None of them had received any prior INCS related instructions.

Table 4. 12-steps technique followed by Rattanawong et al.

	Steps
1.	Shake the spray in the vertical plane*
2.	Remove the dust cap
3.	Blow the nose*
4.	Hold the bottle with the opposite hand from the nostril to be sprayed
5.	Hold the bottle pointing up and replace the hand on the pusher
6.	Put the tip of the nozzle into the nostril and close the other side
7.	Slightly tilt the head forward
8.	Point the tip slightly outwards, away from the septum*
9.	Squirt the spray in to the nose while breathing in*
10	Breathe out through the mouth*
11	Wipe the nozzle with a tissue or handkerchief
12	Replace the cap.

*Recommended five essential steps

Only 6 patients (4%) correctly performed all 12 steps of INCS administration, while 44 patients (29.33%) correctly performed the five recommended essential steps.

Amongst the 12 steps, dust cap removal was correctly performed by all (100%). On the contrary, the most incorrectly performed step was holding the bottle with the opposite hand from the nostril to be sprayed, performed only by 28% although the tip was pointed away from the septum by 56.67%. As for the five essentials steps, squirting the spray in the nose while breathing in (92%) was the most correctly performed step whilst

pointing the tip outward away from the septum was the least properly performed (56.67%). Not pointing the tip away from the septum increased the risk of adverse effects like epistaxis and nasal irritation by 3.6 times as seen in 23 patients (15.33%).

Loh et al.[11] conducted a prospective study on 63 patients using INCS. The six-steps INCS administration technique was used as a standard (Table 5).

Table 5. Six-steps INCS administration technique followed by Loh et al.

Steps	
1.	Clearing of the nose
2.	Shaking of the spray bottle
3.	30-degree forward neck flexion
4.	Correct axis of insertion
5.	Full depression of spray nozzle
6.	Alternating nostrils with each puff.

These steps were demonstrated to the patients and the compliance to the medication emphasized. Compliance was evaluated after 30 days by inquiring and also weighing the amount of medication used during that period, without the patient being aware of this assessment for compliance beforehand. Amongst the 63 patients, 49 (77.8%) patients admitted to forgetting using the medication. Assessing at least 50% compliance, only one patient (1.6%) acknowledged being less than 50% compliant when actually seven patients (11%) had been non-compliant based on the weight of the medication consumed during that period. Significant symptom improvement was noted amongst the more compliant patients who had administered at least 50% of the INCS.

Inspite of the prior demonstration, only 28 patients (44.4%) were able to show the complete six-step nasal spray technique at the follow-up visit. The most common error in administration technique was not clearing the nose by 30 patients (47.6%) followed by not shaking the bottle prior to use by nine (14.3%), failing to maintain proper neck posture by five (7.9%), not depressing the medication fully by four (6.3%) and three (4.8%) did not position the bottle correctly or alternate nostrils between applications.

Loh et. al[11] noted that the INCS efficacy was influenced by the patient's compliance. However, there was a notable inaccuracy in the compliance reported by the patients. They thus stressed the need to ascertain the actual compliance when there was poor response to medication especially because the compliance decreased with time due to chronicity of allergic rhinitis.

A questionnaire-based survey was conducted by Ganesh et al.[7] (Table 6). It involved 103 participants of which 55 were males (53.4%) and 48 females (46.6 %). Their mean age of 45 years (range, 18–82 years; median, 45 years).

Table 6. Questionnaire for survey used by Ganesh et al.

Question	**Fill in or circle applicable answer**
Which nasal spray did/do you use?	
How many sprays and how often?	
What technique did/do you use (circle all that apply)?	Spray nostril with hand on same side / Spray nostril using opposite hand Head down position/ Head up position/ Neutral head position
Did your GP show you how to use your nasal spray?	Yes / No
Do you blow your nose or sniff after using the spray?	Yes / No
Any problem with bleeding after using nasal spray?	Yes / No
If yes, please grade	Minor/ moderate/ severe bleeding
Any problem with irritation after using nasal spray?	Yes / No
If yes, please grade	Minor/ moderate/ severe irritation
If you stopped using your nasal spray, please tell us why.	
On a scale of 1 to 10 (1 being best and 10 being worst) how bad are your nasal symptoms in an average week?	
Do your nasal symptoms affect your sleep?	Yes / No
Do your nasal symptoms affect your work/ study/leisure?	Yes / No

Fifty-four patients (53.5%) affirmed being demonstrated by their general practitioner. Thirty (29.1%) were non-compliant with INCS usage. Non-compliance resulted mostly due lack of symptom resolution in seven and side effects like nasal irritation in 13 and epistaxis in six patients. Amongst these patients, 20 (77%) used the ipsilateral technique whilst six (23%) used the contralateral technique Interestingly, four discontinued due to symptom resolution.[7]

As for the head position, majority of the patients (53.7%) preferred head up position followed by head in neutral position by 25 (26.3%) and head positioned down by 23 (24.2%) (Figure 1). However, with the head up position, the sprays get distributed only to limited area viz. the inferior part of the nose. Limited drug delivery reflects in poor symptom control.[7]

A. Head down position B. Head in neutral position C. Head up position

Figure 1. Different head positions used by patients while administering INCS spray.

Nearly half of the patients (55.4%) used ipsilateral hand for INCS (Figure 2). They were four times likely to have epistaxis and three times more likely to stop using INCS as compared to those using the contralateral hand resulting in poor compliance. [7] Hence the risk of epistaxis and subsequent decrease in compliance was associated with use of the ipsilateral hand.

A. Contralateral hand B. Ipsilateral hand

Figure 2. Side of hand used by patients while administering INCS spray.

Hence, poor symptom control and side effects secondary to head up position and ipsilateral application technique were considered important factors relating to patient's non-compliance. Based on this finding, advising patients to avoid ipsilateral technique and keeping the head either in neutral position or facing down could maximize drug delivery with subsequent symptom control and better compliance. [7]

A component of proper INCS administration technique includes how the spray is aimed in the nasal cavity. Therefore, Treat et al.[9] assessed how patients pointed the INCS in the nose. Most patients (83%) amongst 47 patients aimed INCS incorrectly, even if they had been instructed earlier. The angle at which the spray was directed varied from 50º toward the septum to 43º away from the septum (Figure 3).

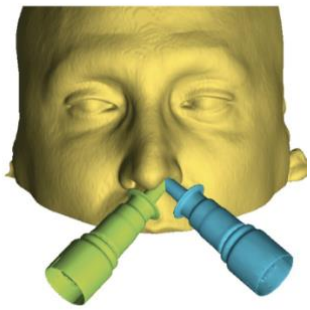


Figure 3: Range of septal angles at which patients sprayed INCS.

However, when the patients received both verbal and written instructions, there was statistically significant improvement in the spray positioning as compared to those who received only one form of instruction or no instructions at all.[9] This suggested the need of re-enforcement of instructions in different forms for patients to better comprehend

the technique. Using the contralateral hand to spray the nose avoids pointing the spray towards the septum and consequently avoids complications.[9]

Interestingly, it is not just the patients but also the healthcare workers who have been found not to strictly follow the required steps. De Boer et. al[16] included 75 healthcare workers from ENT, pediatric department, general practitioner and pharmacies. The steps they demonstrated for INCS administration were matched with the 29 steps outlined in the Dutch protocol (Table 7).[16]

None of the participants performed all the steps correctly. Most of them got 14 out of 29 steps [range 9 – 24, Interquartile range (IQR) 3.5)] correct. Since 29 steps were too exhaustive, the steps were reduced to five essential steps. These steps were considered essential as they were crucial in distribution and efficacy of the nasal spray. They included shaking the bottle, blowing or rinsing the nose, directing the spray away from the nasal septum, breathing in while simultaneously squirting a spray of mist and exhaling through the mouth. [16]

All the essential steps were performed by 27 out of 75 participants (36%). The most consistently performed step was inhaling while squirting the spray in the nose done by 69 out of 75 (92%) participants. Similarly, the subsequent properly performed steps were directing the nozzle outwards [66/75 (88%)] shaking the bottle [61/75 (81%)] and exhaling through the mouth [57/75 (76%)]. The least performed step was blowing the nose prior [46/75 times (61%)]. [16]

Table 7. INCS administration in the Dutch protocol.

Preparation	
1.	Discuss the purpose and action of the medication.
2.	Take off the dust cap.
3.	Firmly shake the bottle.*
4.	Place forefinger and middle finger on both sides of the nozzle and place thumb underneath the bottle.
5.	Point the nozzle upwards and away from yourself.
6.	Squirt a few sprays into the air until you see a cloud of mist.

7.	Blow the nose or rinse the nose with saline if the nose is clogged.*
Administration	
8.	Place forefinger and middle finger on both sides of the nozzle and place thumb underneath the bottle.
9.	A. Keep the head upright and place the nozzle in the nose. B. Use the right hand for spraying in the left nostril and the left hand for spraying in the right nostril.
10.	Point the end of the nozzle slightly outwards, away from the centre ridge of the nose.*
11.	Close the other nostril with your opposite hand.
12.	Squirt a spray of mist in the nose while breathing in.*
13.	Breathe out through the mouth.*
14.	Repeat steps 8 through 13 for the other nostril.
15.	If two sprays per nostril are prescribed, repeat steps 8 through 14 for both nostrils.
16.	Replace the dust cap.
Cleaning	
17.	Wipe the nozzle with a tissue or handkerchief after every use.
18.	Extensively wash the nozzle once a week
19.	Take off the dust cap and nozzle.
20.	Rinse the dust cap and nozzle with warm water
21.	Shake off water
22.	Air- dry the dust cap and nozzle
23.	Replace the nozzle
24.	Firmly shake the bottle
25.	Squirt a few sprays into the air until you see a cloud of mist
26.	Replace the dust cap
Points for attention	
27.	If the nozzle does not spray properly, perform the cleaning steps.
28.	If this does not work, take the spray to the pharmacy. Never puncture the opening.
29.	Check the expiry date on the package and the expiry date after opening

*Recommended five essential steps

Hence, the study uncovered the lack of awareness even amid healthcare workers in demonstrating the technique of INCS administration. Lack of knowledge about the correct technique by the health care worker themselves can result in inadequate instructions to the patients. So, it is important for health care workers to be updated. Following an established protocol and also allocating a personnel for the patient education can bridge this gap. [16]

This study also explained the importance of most of the steps. Nose blowing or cleaning the nose is intended for better distribution of topical steroids although no significant distribution of active substance was found in literature. EPOS 2020[10] rationalized the need for shaking the bottle. Most INCS are in suspension form containing thixotropic agents that increase the viscosity. The viscosity of the drug suspension is decreased when the bottle is shaken consequently forming a mist when sprayed. Keeping head upright and hence avoiding bending the head backwards avoids the medicine to reach the pharynx which could cause irritation and also systemic absorption. Bending the head forward could lead to the medicine trickling anteriorly from the nose. To avoid this, breathing in while spraying with head forward lets the medicine reach the nasal cavity. Directing the nozzle away from the septum allows better distribution of the spray as the lateral nasal wall has comparatively more cilia than the septum and also prevents epistaxis. Using the contralateral hand for spraying causes less mechanical irritation. However, this step is relatively complicated. [16]

1.4. Research Question

The technique of administering INCS spray and compliance seem to be poor. Hence the research question " What are the factors that influence the correct technique and compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis?", was raised.

1.5 Research Objectives

The general objective of the study was

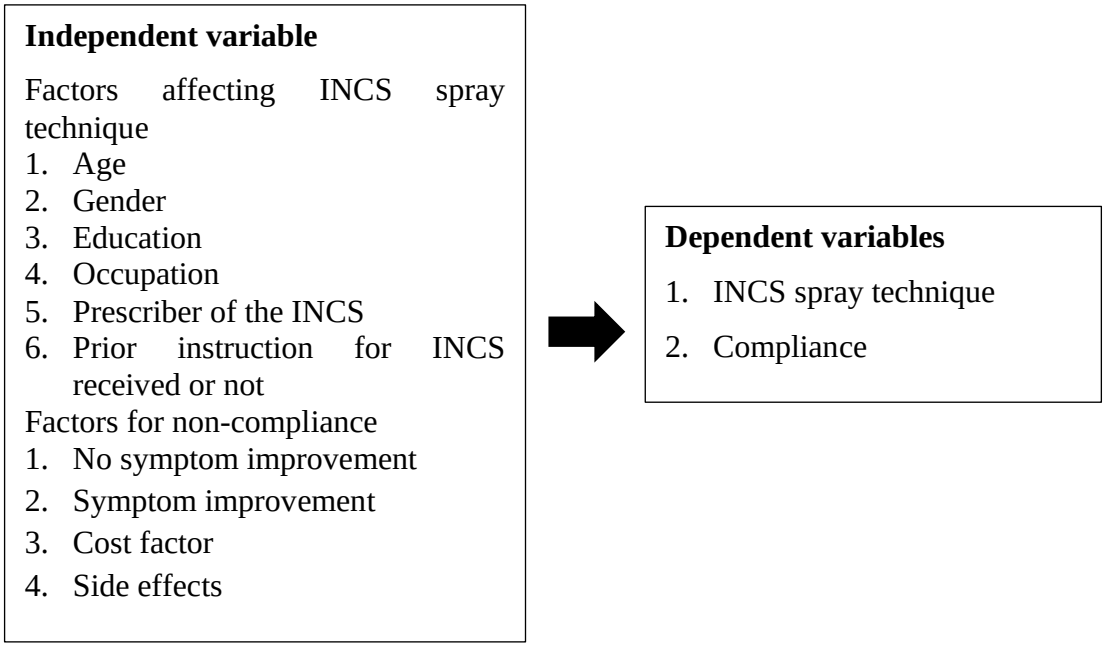
- To identify factors affecting correct technique and compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis.

The specific objectives were

- To identify factors that affect correct technique of use of intranasal corticosteroid spray in patients with allergic rhinitis.
- To identify factors that affect the compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis.
- To assess if the correct technique of use of intranasal corticosteroid spray has any correlation with compliance in patients with allergic rhinitis.

2. Conceptual framework

The following is the conceptual framework of the study.



2.1 Operationalization

Education level	
Informal	Not attended formal education
Basic level	Attended school till class eight
Secondary level	Attended school till 12
Undergraduates	Completed Bachelors' level
Post graduates	Completed Masters' degree.
Frequency of INCS usage	
Regular	INCS usage every day
Most of the times	INCS usage more than four days a week
Sometimes	INCS usage ad hoc or once in a while.
Compliance	
Compliant	Regular INCS user
Non-compliant	INCS usage most of the times or sometimes

Chapter 3: Methodology

3.1 Research Method

The study used quantitative research method.

3.2 Research Design

This was a cross-sectional study as the data was taken only at one point in the study.

3.3 Study period

The study was conducted over 6 months from April 2022 to September 2023.

3.4 Study site and its justification

The study was conducted in the department of ENT-Head and Neck Surgery, Tribhuvan University Teaching Hospital, Maharajgunj Medical Campus, Institute of Medicine, Maharajgunj.

3.5 Study Population

The study population consisted of patients who visited department of ENT-Head and Neck Surgery, Tribhuvan University Teaching Hospital for treatment.

3.6 Sample size

The sample size was calculated using the formula below:

$$\mathbf{n = z^2pq/d^2}$$ [17]

where,

Z= 1.96 at 95% confidence level

p= Prevalence (derived from previous studies)

and q= 1-p

d= Tolerable error margin (a measure of precision)

For this study,

p= 0.9 (based on 90% the prevalence of non-compliance to INCS in a study by KC et al.[8])

q=1-p= 0.1

Tolerable error (d) = 5%

$n= (1.96)^2 X\ 0.9x\ 0.1 / (0.05)^2$

n= 138.29

The total sample size was **138.**

3.7 Sampling Technique

For sampling, convenient sampling technique was used to enroll respondents for the study.

3.8 Sampling Frame

The patients attending Department of ENT-Head and Neck Surgery at Tribhuvan University Teaching Hospital for treatment of allergic rhinitis was the sampling frame.

3.9 Inclusion criteria

Patients with allergic rhinitis with the following criteria were included

1. Patients aged 18 or more; they were independent enough to use the INCS on their own.
2. Currently using INCS or had used INCS in the last three months; this was to avoid disparity of recalling the correct technique of using the INCS.

3.10 Exclusion criteria

Patients with allergic rhinitis with the following criteria were excluded

1. On topical medications other than INCS like steroid drops, decongestant sprays or drops, saline sprays
2. Those with learning disability
3. Those dependent on caretaker for the INCS administration

3.11 Description of research design

The patients meeting the inclusion criteria were initially interviewed using a written questionnaire and observed for the technique of using nasal spray using a check list.

The written questionnaire was divided into two sections The first section dealt with the patient demographics such as age, gender, education level, occupation. The second section was related to the prescriber, instruction given prior to use, the frequency of INCS spray use and if non-compliant, the reason for being non-compliant. The prescriber ranged from ENT doctor, doctor other than practicing ENT or had self-purchased over the counter. Verbal instruction was considered a standard form of instruction. The instructor varied from ENT surgeon, pharmacist or medicine dispenser, friends and family or others. For those not instructed, the options of learning the technique ranged from following patient information leaflet provided in the previous out patient department visit, drug information leaflet provided with the spray bottle, searching the internet, watching YouTube video or as per one's own understanding.

Subsequently, to assess the correctness of nasal spray technique, patients were asked to demonstrate nasal spray application and the steps tallied on the checklist proposed by EPOS 2020.[10] A dummy nasal spray bottle was provided for the demonstration incase patient did not bring his/her own nasal spray.

3.12 Data collection technique

A face-to-face structured interview using written questionnaire was taken to avoid non-response and incomplete data. This was followed by observation of the techniques or steps the patient demonstrated while using nasal sprays, which was tallied to a checklist proposed by EPOS 2020.

3.13 Data collection tools

The data collection tools used were

1. Written questionnaire with structured and filter questions - the questionnaire was prepared by the researcher after reviewing the literature and adapting the relevant information to Nepalese context.
2. Observation checklist as proposed by EPOS 2022.

3.14 Potential biases

There was a likeliness of response bias. To avoid this, each patient was explained the significance of providing accurate information and given assurances on the confidentiality of their data. There was also a probability of recall bias. To overcome this bias, only those patients currently using INCS or had used the INCS within the last three months were included in the study.

3.15 Data management

Data were entered in Microsoft® Excel (Version 16.72) and analyzed using Jamovi (Version 2.3). Descriptive data were analyzed using frequency, percentage, ratio, mean, standard deviation, median and IQR and inferential statistics using Chi-square and Kruskal – Wallis test. The normality was tested by Shapiro–Wilk test. A p-value <0.05 was considered significant. The data were presented in tables and figures.

3.16 Research ethics/ safety issues

The ethical clearance was taken prior to starting the study (Ref no. 449(6-11) E2) from the Institutional Review Committee of Institute of Medicine. The consent to enroll in the study was taken from each patient. There were no safety issues as patients who already had used or using INCS had to demonstrate how they administered the INCS spray.

Chapter 4: Result

A total of 138 patients were enrolled in this study during the study period.

4.1 Patient demographics

The age of the patient ranged from 18 to 72 years. The median age was 30 years with interquartile range 15. There were 71 male patients and 67 female patients with the male female ratio of 1.05:1. Based on the education level, most of them (43.5%) had completed secondary level education (Table 8).

Table 8. Patient demographics

Characteristics		**Number (%)**
Gender	Male	71 (51.4%)
	Female	67 (48.5%)
Age in years	18-30	71 (51.4%)
	31-50	50(36.2%)
	>50	17 (12.3%)
Education level	Informal	11(8%)
	Basic	30 (21.7%)
	Secondary	60(43.5%)
	Undergraduate	29 (21.01%)
	Post graduate	8 (6.5%)

4.2 INCS Prescription and instructions

Most of the patients (97.1%) had been prescribed INCS spray by an ENT doctor and 89.13% of the total 138 patients who had received instructions for INCS mostly by ENT doctor (91%) were verbally instructed. In addition, three of them referred to the drug information leaflet on the spray bottle whilst five followed patient information leaflets which were provided in previous outpatient visit also. Three patients received instruction from doctors other than ENT doctor whilst eight were instructed by the prescription dispenser in the medical shop.

Out of the 138 patients, 14 were not given instruction by any medical professional. So, eight used the INCS as per their own understanding, three followed the instruction on the drug information leaflet available with the spray bottle whilst two followed instruction leaflets provided in earlier out patient visit but were not verbally instructed. One patient browsed the internet for instruction (Table 9).

Table 9. INCS Prescriber and instructions

		Number (%)
Prescriber (138)	ENT doctor	134 (97.1%)
	Respiratory physicians	3 (2.17%)
	Self – prescribed	1 (0.7%)
INCS instruction received (138)	Yes	124(89.8%)
	No	14 (10.1%)
INCS instruction received from (124)	ENT doctor	113 (91.1%)
	Prescription dispenser	8 (6.4%)
	Doctor other than ENT	3 (2.4)
Source of INCS usage when not instructed (14)	As per own understanding	8 (57.1%)
	Drug information leaflet provided with the spray bottle	3 (21.4%)
	Information leaflet provided in earlier outpatient visit	2 (14.2%)
	Browsing the internet	1(7.14%)

4.3 Compliance to INCS spray usage

Out of the 138 patients, 119 (86.2%) were compliant whilst 19 (13.7%) were non-compliant. Amongst the non-compliant patients, ten used it most of the times while nine used it sometimes only (Figure 4).

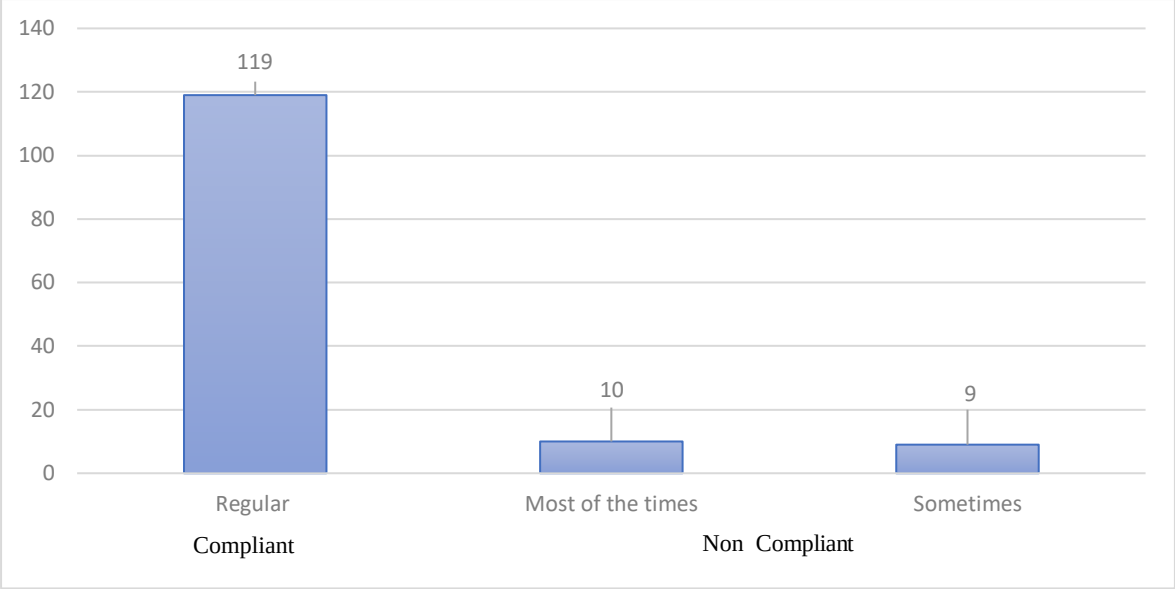


Figure 4. Compliance to INCS administration

The factors for non-compliance were improvement in nasal symptoms in 13, no symptom improvement in two, cost factor in two and side effects like nasal irritation in two. These factors were statistically different between compliant and non-compliant patients (Table 10).

Table 10. Factors for non-compliance to INCS

Compliance to INCS	**Factors for non-compliance**				
	Cost	Symptom improvement	No improvement in symptom	Side effect	*p* value
Compliant	0	0	0	0	<0.001
Non-compliant	2	13	2	2	

Significant *p* value < 0.05

4.4 Correct techniques of INCS administration

When tallying all the steps as laid out by EPOS 2020 protocol, only ten out of 138 (7.2%) of the patients completed all the steps as per EPOS 2020 protocol. Narrowing down the assessment to five essential steps, only 25 (18.1%) followed all the steps correctly.

Removing the cap, gently inserting the nozzle tip into one nostril and repeating the administration of the spray on the other side were followed by all (100%). The least correctly performed steps were keeping the head upright (45%), aiming the nozzle away from the septum (45.6%) and using the right hand to spray the left nostril and vice versa (45.6%) (Table 11). Amongst the five essential steps, the most correctly performed step was shaking the bottle vigorously by 83.3% whilst the least correctly performed step was aiming the nozzle away from the septum by 45.6% (Table 12).

Table 11. Number of well- executed steps as per EPOS 2020 protocol

Steps		**Number (%)**
1	*Gently blow the nose**	76 (55%)
2	*Shake the spray bottle vigorously **	115 (83.3%)
3	Remove the cap	138 (100%)
4	Keep your head upright	63 (45%)
5	Gently insert the nozzle tip into one nostril	138 (100%)
6	*Aim the tip of the nozzle away from the septum** –	63 (45.6%)
7	Use right hand to spray the left nostril and vice versa	63 (45.6%)
8	Do not close the nostril not receiving the medication	80 (60.6%)
9	*While slowly breathing in, press the nasal spray **	90 (65.2%)
10	Apply the number of spray recommended	136 (98.5%)
11	*Take the nozzle out and breathe out through your mouth **	81(58.6%)
12	Repeat the administration step in the other nostril	138 (100%)
13	Clean the spray nozzle and replace the cap	101 (73.1%)

*Essential steps recommended for correct INCS administration.

Table 12. Number of well- executed five essential steps.

Steps		Number (%)
1	Gently blow the nose	76 (55%)
2	Shake the spray bottle vigorously	115 (83.3%)
3	Aim the tip of the nozzle away from the septum	63 (45.6%)
4	While slowly breathing in, press the nasal spray	90 (65.2%)
5	Take the nozzle out and breathe out through your mouth	81(58.6%)

Table 13. Correct technique of INCS spray administration based on various factors

Factors		All steps of EPOS 2020			Five essential steps		
		Correct technique	Incorrect technique	*p* value	Correct technique	Incorrect technique	*p* value
Age in years	18- 30	4	67	0.57	13	58	0.78
	31-50	5	45		*10*	*40*	
	>50	1	16		*2*	*15*	
Gender	Male	14	57	0.57	14	57	0.61
	Female	11	56		11	56	
Academic qualification	Informal	0	11	0.11	0	11	0.26
	Basic level	3	27		7	23	
	Secondary	6	54		11	49	
	Under graduate	1	28		5	24	
	Post-graduate	0	8		2	6	
Prescriber	ENT	10	124	0.57	25	109	0.34
	Respiratory physician	0	1		0	1	
	Doctor other than ENT	0	2		0	2	
	Self-purchase	0	1		0	1	
Instructed by	ENT	9	104	0.55	21	92	0.81
	Respiratory physician	0	1		0	1	
	Doctor other than ENT or respiratory physician	0	2		0	2	
	Prescription dispenser	1	7		2	6	
	No instruction given	0	14		2	12	

Significant *p* value < 0.05

There was no statistical difference in the accuracy of the technique irrespective of the age, gender, prescriber, instruction source or without instruction (Table 13).

Table 14. Correct technique and compliance.

Compliance to INCS	**All steps of EPOS 2020**			**Five essential steps**		
	Correct technique	Incorrect technique	*p* value	Correct technique	Incorrect technique	*p* value
Compliant	9	110	0.72	22	97	0.77
Non-compliant	1	18		3	16	

Significant *p* value < 0.05

There was no statistical difference in compliance with the accuracy of the INCS application technique (Table 14).

Chapter 5: Discussion

Due to chronicity of allergic rhinitis, prolonged use of INCS is needed for it to remain optimally effective. In addition, its administration with a proper, precise technique is equally important. Improper administration technique can result not only in reduced efficacy but also can cause adverse effects hence reducing compliance.[8]

This study was conducted to identify factors that affected the correct technique and compliance of INCS spray usage in patients with allergic rhinitis. Amongst the total of 138 patients, most of them (87.6%) were aged less than 50 years indicating the patients in the productive age group. There was slight preponderance of males over females with the ratio of 1.05:1. Our findings resonated with that of KC et al. [8] and Rattanawong et al.[15] although the latter had included patients with chronic rhinosinusitis also.

In the current study, the most frequent prescriber of the INCS unsurprisingly was the ENT doctor. A few have been prescribed by respiratory physicians also probably because the patient may have associated asthma, although this co-morbid condition was not explored in this study. One had self-prescribed. Self-prescription is common in Nepal as many medicines are easily available over the counter which includes INCS also.

A significant number of patients (89.13%) had been given verbal instructions mostly by ENT doctor (91%). This was better than reported in a UK based survey by Ganesh et al. [7] where only 53.5% of patients stated given demonstration by their general practitioner. Interestingly, in the study in Thailand by Rattanawong et al.[15] none of the patients were instructed by any medical personnels. The other less numbered sources of instructions in our study varied from doctors other than ENT, patient information leaflet, drug information leaflets available with the spray bottle, internet.

In our study, a mere 7.2% (10/138) patients completed all the steps laid out in the EPOS 2020 protocol for correct INCS administration technique. When limiting these to five essential steps, the percentage increased slightly to 18.1% only. This was in concordance to findings from other studies. KC et al.[8] found less than 10% amongst 81 patients correctly demonstrating all the given steps as per the WHO check list.

Similarly, in the study by Rattanawong et al.[15] only six patients (4%) correctly performed all 12 steps of INCS administration, while 44 patients (29.33%) correctly performed the five recommended essential steps. In both these studies, the patients had not received prior INCS administration instruction. Whilst in the study by Loh et. al[11] even with prior demonstration, only 28 patients (44.4%) were able to show the complete six-step nasal spray technique at 30-day follow-up visit.

In our study, there was no difference in the correctness of the INCS administration technique in relation to age, gender, academic qualification, prescriber or source of instruction. This however differed in the study by KC et al.[8] in which only education was found to be significantly associated with correct spray technique after pharmacist led patient education amongst factors namely age, gender, marital status, education and occupation. Although in both studies the maximum number of patients had secondary level education, the nature of instruction received differed. In our study, patients had received only verbal instructions while in their study, pharmacist led individualized education and training was given. Patients are likely to forget if instructions are not re-enforced more so like in our scenario where doctor-patient interaction time is limited due to huge patient overload. Amongst the 63 patients, 49 (77.8%) admitted to forgetting using the medication as per Loh et al.[11] Hence Ocak et al.[14] stressed on assessing the patient on regular interval, re-evaluate the medication and re-emphasize to take the prescribed medicine to address this issue.

Interestingly, the knowledge of healthcare workers on the correct technique of the INCS administration has been doubted by the findings of De Boer et al.[16] Based on the assessment with 29 steps outlined in the Dutch protocol, only about 50% of the 29 steps were performed. Even when narrowing the 29 steps down to five essential steps, only 36 % of the participants could perform all the five steps. So, this study uncovered the lack of awareness even amid healthcare workers in demonstrating the technique of INCS administration. This will definitely culminate into inadequate instructions to the patients. So, it is important for health care workers to be updated.

However, there is a wide variation in the INCS administration techniques that have been adopted in various studies. Benninger et al.[10] therefore rightfully pointed out a lack of a “gold standard” test for the effective INCS spray technique. Not only is there

differences in the protocols but ENT doctors in the same department also had no consensus on a standard technique stated by Ganesh et al.[7] This variation could lead to difficulty in comparing the results of various studies. This study used a widely accepted EPOS 2020 protocol, a detailed one covering all steps from preparation to the core spray technique to cleanliness. Hence, getting all the steps correct could be challenging especially if healthcare workers also are not aware of all the steps. The correctness rate in our study improved once the assessment was done for a less exhaustive five essential steps. Standardizing the INCS application technique helps both patient and healthcare provider to follow the same technique that facilitates proper steroid distribution and maximum effectiveness.[10]

In the current study, 19 (13.7%) patients admitted being non- compliant. This however could not be objectively verified as this was a cross sectional study. In real, the compliance may be lesser. Loh et al. [11] noted that 1.6% patients admitted being non-compliant when actually 11 % were non-compliant when assessed objectively. Ganesh et al.[7] quoted non-compliance of 29.1%.

The factors leading to non-compliance amongst the 19 (13.7%) patients were improvement in nasal symptoms (13), no symptom improvement (two), cost factor (two) and side effects like nasal irritation (two). Ganesh et al.[7] also found lack of symptom resolution and side effects like nasal irritation and epistaxis leading to non-compliance. Interestingly, like in our study, four discontinued due to symptom resolution.[7] Other factors noted by Ocak et al.[14] were persistence of symptoms inspite of taking INCS, side effects, lower education status and also time constraints for self-care due to family obligations if more than two dependent children.

Two patients in our study had side effects namely nasal irritation that led to non-compliance. Nasal irritation and epistaxis are known side effects of INCS particularly if the tip is pointed towards the septum. A study by Rattanawong et. al[15] showed the risk of epistaxis and nasal irritation increased by 3.6 times when pointing the tip towards the septum. These two patients in our study also had the tip pointed towards the septum. So, the side effects and the subsequent reduced compliance were mostly attributed to faulty INCS administration technique. Ganesh et al.[7] noted patients using ipsilateral hand to apply INCS were more likely to develop epistaxis and have poor

compliance because the INCS is likely to be directed towards the more sensitive and vascular septal mucosa when using ipsilateral hand for spraying. [7] So, more attention to this step has been recommended. [15]

Continued education by the treating doctor would help patient understand the need for continued long term treatment for this chronic disease. Training on proper use of nasal sprays and reassessment and reinforcement on regular basis by a medical personnel increase compliance.[14] Loh et. al[11] suggested having add-on specialist educator to counsel patients regarding the nasal spray usage and also other aspect of allergic rhinitis treatment such as the environmental control to increase compliance in a busy clinical set up. This would also avoid any disparity in the technique to be followed. There is also a need for health care workers to be updated regarding the correct technique of administering INCS spray.

Chapter 6: Conclusion

A mere 7.2% (10/138) patients completed all the steps as per EPOS 2020 protocol for correct INCS administration technique. When limiting these to five essential steps, it increased slightly to 18.1% (25/138). The correctness of the INCS administration technique however did not differ with relation to age, gender, academic qualification, prescriber or whether instructions were given or not. Only 13.7% (19/138) patients acknowledged being non- compliant. The factors leading to non-compliance were cost factor, side effects of INCS. Symptom improvement or no improvement both lead to non-compliance. The correctness of the technique did not affect the compliance.

Chapter 7: Limitations of the study

This was a single centre study hence its result cannot be generalized. However, it gave an insight or current status into patients' behavior regarding nasal spray usage. The 13 steps EPOS 2020 protocol was exhaustive and had dissimilarities from other protocols and checklist. However, the essential five key steps were selected for assessment. Compliance to medication was assessed only subjectively which may differ from the actual compliance. The quality of instructions given to the patients which could directly impact the INCS spray technique was not assessed in this study.

Chapter 8: Recommendations

1) To obtain a more generalized idea about patients' behavior towards INCS spray technique, a multicentric study can be carried out.
2) Assessment of the quality of instructions patients receive for INCS spray would help better understand the status of patient education in our context.
3) The practice of poorly administering INCS could be improved by proper patient education with both verbal instruction and physical demonstration of the technique following a standard protocol. A subsequent study assessing the impact of patient education in improving the INCS administration technique can be done.

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Appendices

Budget

S. N.	Budget head	Justification	Units	Total (NRs)
1	Ethical approval fee		-	5,000
2	Man power for data collection and data entry	Monthly fee for data collector/ entrant	3 months	30,000
3	Nasal spray bottles	For demonstration	15	10,000
3	Stationeries	For data collection		5,000
4	Data processing and analysis	Fee for biostatician		8,000
5	Report writing and printing			5,000
6			Total	63,000
7	Contingency fee		5% of total	3,150
Overall Total				66,150

Performa

Questionnaire

Patient demographics

Age Gender
Education Occupation

1. Who prescribed the intranasal corticosteroid nasal spray?
    a. ENT surgeon
    b. Doctor other than ENT surgeon
    c. Self-purchase over the counter
2. Were you instructed to use the nasal spray?
    a. If yes, by whom?
        i. ENT surgeon
        ii. Pharmacist
        iii. Friends and family
        iv. others
    b. If no, how did you start using the spray?
        i. Followed instruction leaflet provided in the earlier opd visit
        ii. Followed instruction leaflet provided with the spray bottle
        iii. Searched in internet
        iv. Watched YouTube video
        v. As per my own understanding
3. How often do you use nasal sprays?
    a. Regularly (everyday)
    b. Most of the times (more than 4 days a week)
    c. Sometimes (once in a while)
4. If not using the nasal spray regularly, what is the reason for not being regular?
    a. Side effect of medicine – epistaxis, dryness of nose, nasal irritation, headache
    b. Symptoms not improving
    c. Symptoms improved
    d. Unavailability of nasal spray
    e. Cost

Observation checklist as proposed by EPOS 2022.

Steps		Place for tick mark		Remarks
		Yes	No	
Before spray administration	Gently blow the nose			
	Shake the spray bottle vigorously			
	Remove the cap			
Head position	Keep your head upright			
Spray tip direction	Gently insert the nozzle tip into one nostril			
	Aim the tip of the nozzle away from the septum – use right hand to spray the left nostril and vice versa			
Free nostril	Do not close the nostril not receiving the medication			
Spray administration and breathing pattern during spray administration	While slowly breathing in, press the nasal spray			
	Apply the number of spray recommended			
After drop administration	Take the nozzle out and breathe out through your mouth			
	Repeat the administration step in the other nostril			
	Clean the spray nozzle and replace the cap			

Consent

INFORMED CONSENT FORM IN ENGLISH

Factors affecting correct technique and compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis

Department of ENT-Head and Neck Surgery

Maharajgunj Medical Campus, Tribhuvan University Teaching Hospital, Institute of Medicine, Maharajgunj, Kathmandu, Nepal

I, ……, male/female of …… years age, hereby confirm that I have read and understood the information sheet and consent form for this research being conducted by Dr Urmila Gurung , and have had the opportunity to ask questions about it.
I hereby declare that,

1. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
2. I understand that the researchers, the IRC and other regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information that will be published or released to the third parties.
3. I agree not to restrict the use of any data or results that arise from this study provided that such use is only for scientific purpose(s).
4. I agree to take part in this study.

Signature (or Thumb impression) of the research participant/Legal Guardian	**Signature (or Thumb impression) of Witness**
Signature : ……	Signature : ……
Name : ……	Name : ……
Date: ……	Date: ……

Investigator's

Signature : ……
Name : …….. Date : ……

INFORMED CONSENT FORM IN NEPALI

सुसूचित मन्जुरीनामा

Factors affecting correct technique and compliance of intranasal corticosteroid spray usage in patients with allergic rhinitis

महाराजगंज चिकित्सा क्याम्पस, त्रि.वि. शिक्षण अस्पताल, चिकित्सा शास्त्र अध्ययन संस्थान

महाराजगंज, काठमाडौं , नेपाल

म …….. उमेर …… वर्षको पुरुष/महिलाले Dr Urmila Gurung ले गर्न लाग्नु भएको यस अनुसन्धान सम्बन्धि संलग्न 'जानकारी पत्र/पुस्तिका' पढेर, सुनेर र प्रश्नोत्तर समेत गरेर यो अध्ययन-अनुसन्धान सम्बन्धमा जानकारी प्राप्त भयो।

- यो अनुसन्धान कार्यमा मेरो सहभागिता मेरो व्यक्तिगत इच्छामा भर पर्ने र मैले चाहेको खण्डमा कुनै पनि बेला यो अनुसन्धान प्रक्रियाबाट बाहिरिन पाउने भन्ने कुरा मैले बुझेको छु। यसको लागि मैले कुनै कारण दिनु नपर्ने र त्यसबाट मैले पाउने सेवा र मेरो कानुनी अधिकारमा असर नपर्ने समेत मलाई बुझाईएकोछ।
- यस अनुसन्धानको प्रतिवेदन वा सम्बन्धित प्रकाशित कृतिहरुमा मेरो कुनै व्यक्तिगत परिचय खुल्ने जानकारी प्रकाशित हुने छैन भन्ने कुरा मैले बुझेकोछु।
- यी सबै कुराहरु जानी-बुझी, म यस अध्ययन-अनुसन्धानमा सहभागी हुन स्वेच्छाले राजी भई यो सुसूचित मन्जुरीनामामा सहिछाप गरेको छु।

<u>सहभागी/सहभागीको अभिभावकको</u>

सही : ……
नाम-थर :
……
मिति : २०७……/……/……

सहभागीको बुढी औंलाको ल्याप्चे छाप

दाँया	बाँया

<u>साक्षीको</u>

सही : ……
नाम-थर : ……
मिति : २०७……/……/……

<u>अनुसन्धानकर्ताको</u>

सही : ……
नाम-थर :
……
मिति : २०७……/……/…

Photographs

1. Using ipsilateral hand for spray

2.Medication spilling out when not breathing in slowly after spraying the nose

3. Nozzle facing towards the septum

4. Spraying with head titled backwards