

Inadequate quality of administration of intranasal corticosteroid sprays

Corine Rollema^{1,2}
Eric N van Roon^{1,2}
Tjalling W de Vries³

¹Department of Clinical Pharmacy and Pharmacology, Medical Centre Leeuwarden, Leeuwarden, The Netherlands; ²Groningen Research Institute of Pharmacy, Department Pharmacotherapy, Epidemiology and Economy, University of Groningen, Groningen, The Netherlands; ³Department of Paediatrics, Medical Centre Leeuwarden, Leeuwarden, The Netherlands

Purpose: Considering the fact that many mistakes are still being made by asthmatic patients when inhaling lung medication, it is important to gain insight into current techniques used to administer intranasal corticosteroid sprays (INCS) in allergic rhinitis patients. In this study, we aimed to get insight into daily use of INCS and to determine if improvement of the technique is required.

Patients and methods: A checklist, based on available patient information leaflets (PILs) and literature, was used to determine the participants' application of the techniques used to administer INCS. These applied techniques were compared with steps described in PILs and recommended essential steps.

Results: In the overall population (64 participants) four participants (6%) carried out all steps as described in the PIL and seven participants (11%) carried out all recommended essential steps.

Conclusion: The technique used to administer INCS is inadequate. Uniform and generally applicable instructions are needed and patients using INCS should be guided better.

Keywords: intranasal corticosteroid sprays, allergic rhinitis, administration techniques, quality of administration

Introduction

Allergic rhinitis (AR) is a common disease, affecting children, adolescents, and adults. The prevalence ranges from 8.5% in children to 27.2% in adults.¹⁻³ Pharmacological agents for AR are aimed at preventing and reducing symptoms. Antihistamines and corticosteroids are available in oral and intranasal dosage forms. In case of corticosteroids, intranasally administered sprays or drops are preferred due to adverse effects (AEs) after systemic use.³

Considering the fact that 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 intranasal corticosteroid sprays (INCS) in AR patients.⁴ Relatively little research has been done about the relation between intranasal administration technique and efficacy. The technique of INCS may affect efficacy, adverse events, and compliance.⁵ In studies, recommendations are imposed to reach highest efficacy and prevent AEs.⁶⁻⁸

In this descriptive, observational study, we aimed to get insight into the current techniques used to administer INCS and to determine if improvement of the technique is required.

Material and methods

Participants were selected from the drug surveillance databases of public pharmacies in Drachten (The Netherlands). Participation was based on the following inclusion criteria:

Correspondence: Corine Rollema
Department of Clinical Pharmacy
and Pharmacology, Medical Centre
Leeuwarden 8901, Henri Dunantweg
2, P.O. Box 888, BR Leeuwarden, The
Netherlands
Tel +31 58 286 3385
Fax +31 58 286 3390
Email corinerollema@gmail.com

patients were aged 8–30 years old and had been using INCS for a minimum period of 1 week. Patients were excluded when they were unable to complete study procedures or did not understand and speak the Dutch language fluently. The following active compounds were included: beclomethasone, budesonide, fluticasone furoate, fluticasone propionate, and mometasone furoate, brand name and generic dosage forms were included. Eligible patients were approached randomly and actively asked if they wanted to participate in the study. When patients wanted to participate, the application technique of the INCS was directly observed in a face-to-face interview. The objective of the interview was to gain insight into the techniques used to administer INCS. All participants were interviewed and observed by the same investigator. The administration techniques were scored using a checklist. This checklist included all maneuvers for daily administration of INCS as indicated in the patient information leaflet (PIL) of the spray the participant used. The complete instruction for administration of INCS in PILs contained a maximum of eleven steps; however for some steps different instructions were described and not all steps were described in the different PILs (Table 1). The recommended essential steps were based on available literature (Table 2).^{6–8} In the analysis, descriptive statistics were used and a significant difference between populations could not be proved in this study. The study protocol was approved by the medical ethics committee of Medical Centre Leeuwarden (MCL). All patients and, if necessary, their caregivers, gave written informed consent.

Results

We analyzed the application of the recommended maneuvers in 64 participants by direct observation of intranasal administration (Table 1). Participant characteristics are presented in Table 3. Overall, the majority of participants were female, used an INCS for AR on a daily basis, got prescribed mometasone furoate, and had an average age of 18.4 years. Only four participants (6%) carried out all steps as described in the PIL. Taking the dust cap off and hand positioning were carried out as described in the PIL by all participants. Shaking the device, closing the nostril, inhaling, and replacing the dust cap were carried out as described in the PIL by the majority of the participants (91%; 73%; 98%; and 97%, respectively). Approximately half of the participants blew their nose (48%), had correct spray positioning (45%), and used correct technique for exhalation (54%) and cleaning (52%). Head positioning was carried out according to the PIL in approximately 10% of the participants (13%).

Table 1 Steps in PIL

Steps in PIL	Instruction carried out, n (%)
1. Shake the spray	58 (91%)
2. Remove the dust cap	64 (100%)
3. Blow the nose	31 (48%)
4. Instruction for hand position	64 (100%)
5. Instruction for closing the nostril* <ul style="list-style-type: none"> Put the tip of the nozzle into the nostril and close the other nostril Put the tip of the nozzle into the nostril 	47 (73%)
6. Instruction for head position* <ul style="list-style-type: none"> Slightly tilt forward No instruction 	7 (13%)
7. Instruction for position of the spray* <ul style="list-style-type: none"> Point the end of the nozzle slightly outwards, away from the septum No instruction 	10 (45%)
8. Inhale instruction* <ul style="list-style-type: none"> Squirt a spray of mist in the nose while breathing in No instruction 	61 (98%)
9. Exhale instruction* <ul style="list-style-type: none"> Breathe out through the mouth No instruction 	30 (54%)
10. Clean instruction* <ul style="list-style-type: none"> Wipe the nozzle with a tissue or handkerchief No instruction 	29 (52%)
11. Replace the dust cap	62 (97%)

Notes: The eleven steps for administration of INCS as described in the PIL, available for patients in The Netherlands. In PILs of different working compounds and manufacturers, different instructions for the same step are described (indicated with *). It is indicated how many participants (n, %) carried out the instruction per step.

Abbreviations: PIL, patient information leaflet; INCS, intranasal corticosteroid sprays.

Table 2 Recommended essential steps

Essential steps	Instruction carried out, n (%)
1. Shake the spray	58 (91%)
2. Blow the nose	31 (48%)
3. Point the end of the nozzle slightly outwards, away from the septum	26 (44%)
4. Squirt a spray of mist in the nose while breathing in	63 (98%)
5. Breathe out through the mouth	31 (48%)

Notes: Described are the five recommended essential steps for administration of INCS, data from Benninger et al, Jang et al and Tay et al.^{6–8} It is indicated how many participants (n, %) carried out the instruction per step.

Abbreviation: INCS, intranasal corticosteroid sprays.

We analyzed the application of the recommended steps for daily administration of INCS as described (Table 2). In this population seven participants (11%) carried out all the recommended essential steps. Shaking the device and inhaling were carried out by almost the whole population (91%

Table 3 Participant characteristics

	Overall (n=64)
Gender, n (%)	
Male	19 (30%)
Female	45 (70%)
Age (years), range (median)	8–30 (19)
Indication, n (%)	
Allergic rhinitis	40 (63%)
Inflammation of nasal mucosa	5 (8%)
Nasal polyp	1 (2%)
Other ^a	18 (28%)
Active compound, n (%)	
Mometasone furoate	26 (41%)
Fluticasone propionate	16 (25%)
Fluticasone furoate	14 (22%)
Beclometasone	6 (9%)
Budesonide	2 (3%)

Notes: ^aOther indications, as given by the participants, included cold complaints, asthma, and keeping the acoustic duct open.

and 98%, respectively). Approximately half of the patients blew their nose (48%), had correct spray positioning (44%), and used correct exhalation technique (48%).

Discussion

We found that most patients did not take their INCS as described in the instructions, and they received instructions as described in the PIL after the interview. The techniques they used were not according to the PILs or the recommended essential steps, thereby the quality of administration can be denominated as inadequate in most patients.

Although there has been relatively little research about the relation between a particular administration technique and efficacy, it may be expected that the administration technique of INCS may affect efficacy, occurrence of AEs, and compliance.⁵ Benninger et al tried to find evidence regarding how to instruct patients to use INCS.⁶ No clear evidence was found regarding head positioning and spray position, but based on findings in their review, recommendations for the use of INCS were established. It is recommended to have the head in a neutral position when using INCS spray, because when the head is tilted back, the intranasal corticosteroid could flow into the throat and cause throat irritation and absorption in the gastrointestinal tract.^{6,7} A Cochrane review showed an increased risk of occurrence of epistaxis using an INCS compared to placebo or no intervention (RR 2.74, 95% CI 1.88–4.00; 2,508 participants; 13 studies; high quality evidence).⁹ To prevent epistaxis it is recommended to point the nozzle outwards, away from the nasal septum.⁶ In the study

of Ganesh et al, applying INCS with the ipsilateral hand technique (for example right hand to right nostril) was compared with the contralateral hand technique (for example right hand to left nostril) and these data suggest that the contralateral technique affects AEs and patient compliance in a positive way.⁵ Based on in vitro computational fluid dynamics, Jang et al evaluated the effect of nasal inspiratory airflow on the distribution of intranasal corticosteroids. They found that using a simultaneously gentle inspiration technique improved the distribution of intranasal corticosteroids in the nasal cavity and that there was better distribution beyond the nasal valve. Sniffing too hard can result in additional turbulence generated in the nasal cavity and thereby deposition in the throat.⁸

Although less thorough research has been done about the best application technique, these recommendations can lead to a structural, standardized protocol for administration of INCS.

Our data indicate that many steps for administration of INCS are skipped or not executed. An explanation for this could be that patients are not fully aware of the existence of a comprehensive set of instructions for administering INCS in PILs. Other reasons for not carrying out all steps of administration can be sloppiness, forgetting how to do it or unclear instructions given by doctor or pharmacist. It is unclear now how patients determine how to use their INCS. Patients using INCS should be better informed about the instructions for correct administration.

One of the influencing factors is the insufficient, incomplete information in PILs. Recently we studied all PILs of INCS of different Dutch manufacturers. In total, 31 PILs were analyzed and the complete instruction for administration of INCS consists of ten steps. Only in one PIL all ten steps for administration were described. Four of the ten steps included a missing instruction in some PILs. Three of the ten steps were described differently in some PILs.¹⁰ We conducted the same study in the UK, here 21 PILs were analyzed and comparable results were gathered.¹¹ To achieve a uniform technique for the administration of INCS, complete and uniform instructions are needed in different PILs.

Either way, patients need to administer the medication optimally. This can be achieved by an additional instruction comparable with the existing instructions for adequate inhalation of lung medication.

Conclusion

In conclusion, this study shows that the technique used to administer INCS is inadequate in most patients studied.

For this reason, more attention should be given to this in health care. Uniform and generally applicable instructions are needed and patients using INCS should be guided better.

Ethics approval and informed consent

The study protocol was approved by the medical ethics committee of MCL. All patients and, if necessary, their caregivers gave written informed consent.

Data sharing

This manuscript contains all data used for the presented results (Tables 1–3). No additional unpublished data are available.

Author contributions

All authors contributed to data analysis, drafting and revising the article, gave final approval of the version to be published, and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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