

# The use of nasal over-the-counter agents in the evaluated Polish population. The underrated role of the pharmacist in patient education on medical treatment in patients with allergic rhinitis

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## Abstract

**Introduction:** The goal of treatment in allergic rhinitis is a complete elimination of symptoms or achieving significant clinical improvement. The role of the pharmacist has been receiving particular attention in terms of the initial diagnosis and treatment of allergic rhinitis patients and their sufficiently early referral to a specialist in case of persistent symptoms.

**Aim:** This study attempted to estimate the rates of nasal OTC use in patients diagnosed with allergic rhinitis.

**Material and methods:** Study population was 18,578 subjects (4,192 patients diagnosed with AR and 14,386 healthy controls): children aged 6–7 years, adolescents aged 13–14 years, and adults aged 20–44 years. We used translated and validated versions of ECRHS and ISAAC questionnaires.

**Results:** The rates of nasal decongestant use in the allergic rhinitis group were 60.4% in children, 50.7% in adolescents, and 43.0% in adults, with these figures significantly higher than in the control group ( $p < 0.05$ ). The most common nasal agent was *Oxymetazoline* and *Xylometazolini hydrochloridum* 0.1%.

**Conclusions:** Over a half of the evaluated allergic rhinitis patients used nasal decongestants, which poses a potential risk of uncontrolled side effects. There is an urgent need to introduce patient education on medical treatment.

**Key words:** allergic rhinitis, over-the-counter (OTC) nasal decongestants, patient education on medical treatment or pharmacist education.

## Introduction

Allergic rhinitis (AR) is the most common allergic condition [1, 2]. According to the 2008 Allergic Rhinitis and its Impact on Asthma (ARIA) document, over 500 million people worldwide suffer from AR [1, 3]. The Epidemiology of Allergic Diseases in Poland (ECAP) study showed that, in Poland, over 14.5 million people suffer from rhinitis, including over 8.5 million suffering from AR [4]. AR is a global health problem that affects the quality of life and ability to work of people all over the world. In clinical terms, AR is defined as a set of symptoms induced by an IgE-mediated inflammatory reaction in the nasal mucosa following allergen exposure. The ARIA document classi-

fied the severity of AR as “mild” or “moderate-severe” [1]. AR can be considered to be a systemic condition. Nasal dysfunction leads to physical and psychological discomfort. Symptoms of allergic rhinorrhoea and/or nasal congestion affect the patients’ overall intellectual and physical performance as well as their effectiveness when working and learning. During periods of AR exacerbation, patients report feeling ill, to the extent comparable with bronchial asthma (AO). One key problem for AR patients is difficulty sleeping, in the form of difficulty falling asleep and waking up at night, which leads to permanent fatigue, exhaustion, and increased daytime sleepiness, significantly lowering the quality of

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life. In comparison with conditions such as hypertension and diabetes mellitus, AR is associated with considerably higher rates of reduced patients' quality of life (with lowered quality of life reported by 8.8% of patients with hypertension, 16.7% of patients with type 2 diabetes mellitus, and 26.6% of patients with AR) [5].

Another important aspect of AR is a number of factors (including organizational factors) that limit patients' access to specialists and, as a consequence of the burdensome symptoms, prompt the patients' attempts at self-medication. Recent publications show a widespread interest in coordinated patient care at large and integrated care in AR and bronchial asthma patients in particular. There has been a great emphasis on patient education regarding the nature and symptoms of their disease as well as treatment goals and self-management. The role of the pharmacist has been receiving particular attention in terms of the initial diagnosis and treatment of AR patients and their sufficiently early referral to a specialist in case of persistent symptoms. This is very important because often it is precisely the pharmacist who is the first step on an AR patient's pathway to diagnosis and treatment [5–7]. Hence, it seems reasonable to direct organizational efforts within the healthcare system towards establishing specialist training courses for pharmacists, who are the first line of contact for AR patients seeking over-the-counter (OTC) treatments.

## Aim

The purpose of this study was to estimate the rates of nasal OTC use in patients diagnosed with AR in comparison with those in a control group.

## Material and methods

This study was conducted in individuals randomly selected from by the Polish Ministry of the Interior and Administration from the PESEL (Polish citizen identification number) database. The tools used in our study were *European Community Respiratory Health Survey II* (ECRHS II) and *International Study of Asthma and Allergies in Childhood* (ISAAC) questionnaires adapted for Middle and Eastern Europe, which had been used as part of a larger project, titled *Implementation of a System for the Prevention and Early Detection of Allergic Diseases in Poland*. The project was conducted in eight metropolitan areas (Gdansk, Wroclaw, Poznan, Katowice, Krakow, Lublin, Bialystok, Warsaw) and in rural regions (Krasnostawski county) and had two stages. The first stage involved grouping the 22,500 respondents based on their questionnaire responses with the use of Personal Digital Assistant (PDA) tool; the second stage involved an outpatient evaluation of 7,000 patients, who underwent additional assessments: skin prick tests (birch, grasses/cereals, *Dermatophagoides pteronyssinus* and *Derma-*

*tophagoides farinae*, moulds (set I) (*Botrytis cinerea*, *Cladosporium herbarum*, *Alternaria tenuis*, *Curvularia lunata*, *Fusarium moniliforme*, *Helminthosporium*), moulds (set II) (*Aspergillus fumigatus*, *Mucor mucedo*, *Penicillium notatum*, *Pullularia pullulans*, *Rhizopus nigricans*, *Serpula lacrymans*), cat, dog, moulds (*Cladosporium herbarum*, *Alternaria tenuis*) control, histamine), spirometry, and peak nasal inspiratory flow (PNIF). The clinical diagnosis of AR was verified based on the criteria included in the ARIA document.

The study group comprised 18,578 subjects (including 14,386 controls and 4,192 patients diagnosed with AR). The AR subgroup included 1,065 children aged 6–7 years (25.4%), 1,160 adolescents aged 13–14 years (27.6%), and 1,967 adults aged 20–44 years (46.9%); collectively, there were 2,124 (50.6%) females and 2,068 (49.3%) males. A total of 3,864 of AR patients (92.1%) lived in large metropolitan areas, whereas 328 (7.8%) patients lived in rural regions. The control group exhibited similar rates of these individual variables, with 3,429 (23.8%) children, 3,554 (24.7%) adolescents, and 7,403 (51.4%) adults; the control group comprised 7,866 (54.6%) females and 6,520 (45.3%) males; with 12,659 (87.9%) urban and 1,727 (12.0%) rural inhabitants.

The study was approved by the Medical University of Warsaw Institutional Review Board (KB/206/2005) and the Inspector General for the Protection of Personal Data.

## Statistical analysis

The statistical analysis was performed with the use of contingency tables and compared the rates of using appropriate medication in the selected study subgroups (AR vs. controls, urban vs. rural inhabitants, males vs. females, and the three age groups: 6–7, 13–14, and 20–44 years). A proportion test (prop. test function in R software) was conducted to demonstrate significant differences in proportions between study subgroups; subgroups were compared in pairs (controls-AR patients, urban-rural areas, sex) as well as in larger sets (age groups). The significance threshold was set at 0.05. R statistical software was used for all computing and graphics in this study.

## Results

Over a half of the AR study group reported nasal congestion (Table 1) that had persisted for 12 months. The resulting difference with respect to the control group was statistically significant ( $p < 0.05$ ). Nearly 10% of the entire study population used decongestants, with the vast majority of those people living in urban areas. All subjects reported nasal congestion. This was particularly noticeable in the adult subpopulation, with adults suffering from this symptom for up to 4 weeks a year (3 weeks in women and 4 weeks in men). Urban residents reported a nearly half a week longer duration of symptoms than

**Table 1.** Nasal obstruction and the rates of decongestant use

Allergic rhinitis group					
Are you prone to having a blocked nose for several weeks or months a year, with no other associated symptoms (itching, sneezing, RUNNY NOSE, itchy-watery eyes)?					
Age: 6–7 years		Age: 13–14 years		Age: adults	
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
573	53.8	593	51.1	1,049	53.3
Sex: female			Sex: male		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
1,105	52.0	1,110	53.6		
Place of residence: metropolitan areas			Place of residence: rural areas		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
2,085	53.9	130	39.6		
Have you used any medication for your blocked nose within the last 12 months?					
Age: 6–7 years		Age: 13–14 years		Age: adults	
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
644	60.4	589	50.7	846	43.0
Sex: female			Sex: male		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
1,060	49.9	1,019	49.2		
Place of residence: metropolitan areas			Place of residence: rural areas		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
1,919	49.6	160	48.7		
Control group					
Are you prone to having a blocked nose for several weeks or months a year, with no other associated symptoms (itching, sneezing, RUNNY NOSE, itchy-watery eyes)?					
Age: 6–7 years		Age: 13–14 years		Age: adults	
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
383	11.1	281	7.9	695	9.3
Sex: female			Sex: male		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
708	9.0	651	9.8		
Place of residence: metropolitan areas			Place of residence: rural areas		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
1,279	10.1	80	4.6		
Have you used any medication for your blocked nose within the last 12 months?					
Age: 6–7 years		Age: 13–14 years		Age: adults	
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
1,122	32.7	763	21.4	1,351	18.2
Sex: female			Sex: male		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
1,815	23.0	1,421	21.7		
Place of residence: metropolitan areas			Place of residence: rural areas		
<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
2,929	23.1	307	17.7		

**Table 2.** The use of nasal decongestants (OTC) in the allergic rhinitis group

OTC used	Age						Sex						Place of residence					
	6-7 years		13-14 years		Adults		Females		Males		Metropolitan areas		Rural areas					
	n	%	n	%	n	%	n	%	n	%	n	%	n	%				
<b>Oxymetazoline (Acartar nasal spray)</b>	<b>45</b>	<b>6.9</b>	<b>128</b>	<b>21.6</b>	<b>170</b>	<b>20.0</b>	<b>179</b>	<b>16.7</b>	<b>164</b>	<b>16.0</b>	<b>324</b>	<b>16.8</b>	<b>19</b>	<b>11.8</b>				
Oxymetazoline (Afrin nasal spray)	14	2.1	38	6.4	50	5.8	47	4.4	55	5.3	97	5.0	5	3.1				
Oxymetazoline (Nasivin 0.01% nasal drops)	99	14.6	33	5.5	24	2.8	71	6.6	81	7.9	140	7.2	12	7.4				
Oxymetazoline (Nasivin 0.025% nasal drops)	94	14.5	36	6.0	20	2.3	63	5.9	87	8.5	139	7.2	11	6.8				
Oxymetazoline (Nasivin 0.05% spray)	40	6.1	28	4.7	29	3.4	49	4.5	48	4.7	92	4.7	5	3.1				
Oxymetazoline (Nasivin soft 0.01% nasal drops)	29	4.4	6	1.0	10	1.1	21	1.9	24	2.3	39	2.0	6	3.7				
Oxymetazoline (Nasivin soft 0.025% nasal drops)	13	2.0	6	1.0	4	0.4	16	1.4	7	0.6	21	1.0	2	1.2				
Oxymetazoline (Nasivin soft 0.05% nasal drops)	74	1.7	32	1.5	33	1.1	15	1.4	15	1.4	29	1.5	1	0.6				
Xylometazolini hydrochloridum (Otrivin 0.05% spray)	98	1.1	57	7.0	48	5.0	80	7.4	79	7.7	150	9.9	9	6.8				
<b>Xylometazolini hydrochloridum (Otrivin 0.1% nasal spray)</b>	<b>59</b>	<b>9.1</b>	<b>70</b>	<b>11.8</b>	<b>104</b>	<b>12.2</b>	<b>115</b>	<b>10.7</b>	<b>118</b>	<b>11.5</b>	<b>226</b>	<b>11.7</b>	<b>7</b>	<b>4.3</b>				
Xylometazolini hydrochloridum (Otrivin 0.1% nasal drops)	29	4.4	45	7.5	64	7.6	62	5.8	76	7.4	132	6.8	6	3.7				
Xylometazolini hydrochloridum (Oxalin 0.025% nasal drops)	13	2.0	10	1.6	12	1.4	15	1.4	20	1.9	31	1.6	4	2.4				
Xylometazolini hydrochloridum (Oxalin 0.025% nasal gel)	5	0.7	6	1.0	5	0.5	9	0.8	7	0.6	14	0.7	2	1.2				
Xylometazolini hydrochloridum (Oxalin 0.05% nasal drops)	11	1.7	12	2.0	15	1.7	24	2.2	14	1.3	36	1.8	2	1.2				
Xylometazolini hydrochloridum (Oxalin 0.05% nasal gel)	8	1.2	4	0.6	9	1.0	15	1.4	6	0.5	21	1.0	0	0				
Xylometazoline (Xylogel 0.05% nasal gel)	29	4.4	21	3.5	14	1.6	39	3.6	25	2.4	57	2.9	7	4.3				
Xylometazoline (Xylogel 0.1% nasal gel)	15	2.3	26	4.3	52	6.1	54	5.0	39	3.8	86	4.4	7	4.3				
Xylometazoline 0.05% nasal drops	29	4.4	44	7.4	25	2.9	15	4.6	47	4.7	86	2.3	12	3.7				
Xylometazoline 0.1% nasal drops	8	1.2	38	6.4	98	11.5	71	6.6	73	7.1	130	6.7	14	8.6				
Xylorin nasal gel	5	0.3	5	0.8	13	1.0	8	0.7	8	0.7	14	0.7	2	1.2				

**Table 3.** The use of nasal decongestants (OTC) in the control group

OTC used	Age						Sex						Place of residence					
	6-7 years		13-14 years		Adults		Females		Males		Metropolitan areas		Rural areas					
	n	%	n	%	n	%	n	%	n	%	n	%	n	%				
<i>Oxymetazoline (Acatar nasal spray)</i>	64	5.6	123	16.0	262	19.3	240	13.1	209	14.6	415	10.1	34	4.6				
<i>Oxymetazoline (Afrin nasal spray)</i>	25	2.2	28	3.6	66	4.8	63	3.4	56	3.9	111	3.7	8	2.5				
<i>Oxymetazoline (Nasivin 0.01% nasal drops)</i>	141	12.5	35	4.5	63	4.6	131	7.1	108	7.5	217	7.3	22	7.1				
<i>Oxymetazoline (Nasivin 0.025% nasal drops)</i>	143	12.7	23	2.9	32	2.3	105	5.7	93	6.5	179	6.0	19	6.1				
<i>Oxymetazoline (Nasivin 0.05% spray)</i>	84	4.7	29	3.7	40	2.9	89	4.8	64	4.4	146	4.9	7	2.2				
<i>Oxymetazoline (Nasivin soft 0.01% nasal drops)</i>	40	3.5	14	1.8	14	1.0	33	1.8	35	2.4	65	2.2	3	0.9				
<i>Oxymetazoline (Nasivin soft 0.025% nasal drops)</i>	54	4.8	6	0.7	6	0.4	38	2.0	28	1.9	59	2.0	7	2.2				
<i>Oxymetazoline (Nasivin soft 0.05% nasal drops)</i>	15	1.3	7	0.9	4	0.2	16	0.8	10	0.7	26	0.8	0	0				
<i>Xylometazolini hydrochloridum (Otrivin 0.05% spray)</i>	116	10.3	67	8.7	83	6.1	150	8.2	116	8.1	268	9.1	13	4.2				
<i>Xylometazolini hydrochloridum (Otrivin 0.1% nasal drops)</i>	77	6.8	74	9.6	164	12.1	181	9.9	134	9.4	300	10.2	15	4.8				
<i>Xylometazolini hydrochloridum (Otrivin 0.1% nasal drops)</i>	45	4.0	56	7.3	87	6.4	103	5.6	85	5.9	164	5.5	24	7.7				
<i>Xylometazolini hydrochloridum (Oxalin 0.025% nasal drops)</i>	24	2.1	10	1.3	8	0.5	22	1.2	20	1.4	37	1.2	5	1.6				
<i>Xylometazolini hydrochloridum (Oxalin 0.025% nasal gel)</i>	25	2.2	3	0.3	14	1.0	28	1.5	14	0.9	33	1.1	9	2.9				
<i>Xylometazolini hydrochloridum (Oxalin 0.05% nasal drops)</i>	14	1.2	12	1.5	31	2.2	36	1.9	21	1.4	47	1.6	10	3.2				

**Table 3.** The use nasal decongestants (OTC) in the control group

OTC used	Age						Sex				Place of residence			
	6-7 years		13-14 years		Adults		Females		Males		Metropolitan areas		Rural areas	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
<i>Xylometazolini hydrochloridum</i> (Oxalin 0.05% nasal gel)	6	0.5	7	0.9	16	1.1	17	0.9	12	0.8	25	0.8	4	1.2
<i>Xylometazoline</i> (Xylogel 0.05% nasal gel)	5	3.6	11	2.3	18	3.0	61	3.3	40	2.8	94	3.2	7	2.2
<i>Xylometazoline</i> (Xylogel 0.1% nasal gel)	41	1.5	18	4.1	42	4.2	72	3.9	35	2.4	93	4.1	14	4.8
<i>Xylometazoline</i> 0.05% nasal drops	51	4.5	52	4.7	41	3.0	77	4.2	67	4.7	126	4.2	18	5.8
<i>Xylometazoline</i> 0.1% nasal drops	18	1.6	69	8.9	164	12.1	149	8.1	102	7.1	207	7.0	44	14.2
<i>Xylorin</i> nasal gel	3	0.2	4	0.5	13	0.9	10	0.5	10	0.7	17	0.5	3	0.9

rural area inhabitants. Such symptomatic periods were reported three times a year on average.

The medication most commonly used in the AR subgroup was *Oxymetazoline*: with nearly 22% of adolescents and 20.0% of adults (Tables 2 and 3). *Oxymetazoline* users were mainly women and urban inhabitants. These proportions were only slightly lower in the control group, with 16% of adolescent and 19.3% of adult users. *Oxymetazoline* was more commonly used by males and decidedly more commonly by those inhabiting large metropolitan areas. The second most common decongestant was *Xylometazolini hydrochloridum* 0.1%, with the rates of its use among children, adolescents, and adults equal to 9.1%, 11.8%, and 12.2%, respectively. The rates of *Xylometazolini hydrochloridum* 0.1% use were also decidedly higher among urban inhabitants. These proportions were only slightly lower in the control group, with nearly 8% of children, 9.6% of adolescents, and 12.1% of adults using *Xylometazolini hydrochloridum* 0.1%. The rates of use of this drug were almost two-fold higher in urban inhabitants, which was a significant difference in comparison with the rates of its use in rural area inhabitants ( $p < 0.05$ ).

### Discussion

Allergic rhinitis is a global health problem, and the prevalence of this condition is high. AR affects all age groups, although it is most common in young individuals. AR is a chronic condition, which affects the patients' social life, study, and work. Therefore, it is an important public health issue and is most commonly viewed as a serious economic problem, which is associated with the rates of absence from work and a lower work efficiency [7, 8].

The goal of treatment in AR is a complete elimination of symptoms or achieving significant clinical improvement. The management of patients with AR includes patient education (on the issue of avoiding the triggering allergen), medical treatment, and allergen-specific immunotherapy. According to the 2010 ARIA guidelines, the most important class of drugs for the treatment of AR patients are local (nasal) glucocorticoids and second-generation antihistamines. Oral antihistamines are the first line of treatment for mild AR and are used in combination with drugs of other classes in more severe presentations [2, 3, 7].

Currently, there are a number of OTCs approved for AR treatment, and patients often use these drugs for relieving AR symptoms. In our study population, nasal decongestants proved to be the most commonly used class of OTCs. They were used both by those with AR and by others, which was most likely due to the rapid decongestant effect of these drugs. Nasal decongestants are the oldest drugs used in the treatment of rhinitis. They are alpha-adrenergic receptor agonists and, consequently, induce smooth muscle contraction and vasoconstriction,

which rapidly reduces nasal mucosal oedema. The effect of these drugs is very rapid and persists for anywhere from several to about a dozen hours. However, using them for over 7–10 days induces tachyphylaxis, which manifests with pathological (paradoxical) nasal mucosal oedema. Their chronic use leads to drug-induced rhinitis. In patients with AR, in case of severe nasal mucosal oedema, nasal decongestants may be only used sporadically, very briefly, and in combination with local glucocorticoids [1, 3, 7].

Recent literature reports have discussed the issue of multidisciplinary care for patients with AR, the purpose of which is to achieve and maintain optimal control of symptoms and a greater patient satisfaction. Pharmacists seem to be an important part of interdisciplinary care for AR patients [1].

According to the experts who composed the ARIA document as well as health care professionals, pharmacists are suitable for diagnosing AR symptoms and suggesting appropriate treatment as well as referring the patient to a specialist, which is very important in case of treatment failure [7, 8]. In 2017, Tan *et al.* conducted a study in 296 pharmacy customers who purchased nasal medications. That study demonstrated that 69.9% of the evaluated patients used exclusively self-medication with OTCs. Sixty-eight percent of patients complained of AR symptoms while only 44.3% of those had physician-diagnosed AR. The most commonly reported symptom in that study group was nasal obstruction (73.6%), and the most commonly purchased medications were antihistaminic agents (44.3%). The authors of that study emphasized the important issue of self-medication by patients with AR, which might result in inappropriate treatment and disease complications. They also stressed the importance of pharmacist education in terms of AR diagnostics and treatment as well as that of the pharmacists becoming actively engaged in AR patient care [4]. Patients with AR symptoms relatively often self-medicate and for this purpose they choose OTCs. Overall, people who buy AR medications can be divided into three groups: those with symptoms of AR but with no diagnosis, those with AR symptoms who are accurately self-diagnosed with AR, and those with physician-diagnosed AR [8]. Patients with physician-diagnosed AR typically follow a certain physician-recommended treatment regimen, and the role of a pharmacist in these cases involves suggesting suitable OTCs, which could lower the cost of treatment. In case of those with AR without a diagnosis, the pharmacist can establish a history-based, preliminary diagnosis, differentiate between the symptoms of allergic rhinitis and infectious rhinitis, and suggest appropriate treatment, or refer the patient to a doctor. The pharmacist's role in the diagnosis and treatment of allergic rhinitis involves: alleviating symptoms and improving the quality of life, assessing the safety of treatment with the OTCs dispensed, determining the need to consult a doctor, and deciding

on when the drug should be discontinued. According to ARIA document experts, the inclusion of pharmacists in patient care helps reduce the risk of medication overdose.

## Conclusions

We believe it worthwhile to consider introduction of specialist training sessions for pharmacists (as they are the first line of contact for AR patients seeking treatment), addressing two subject areas:

- 1) the diagnosis and treatment of AR in order to alleviate its symptoms, assessing the safety of medications dispensed without a prescription, determining the need for a doctor consultation, and deciding when the medication should be discontinued,
- 2) effective communication with patients suffering from AR regarding the topics mentioned above.

## Conflict of interest

The authors declare no conflict of interest.

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