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Increased frequency of rhinitis medicamentosa due to media advertising for nasal topical decongestants

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Abstract. *Aim*: The aim of this study was to investigate the frequency of rhinitis medicamentosa (RM) in patients attending the ENT outpatient clinic of the General Hospital of Rethymnon (Crete, Greece) before and after the launch of an intensive nasal decongestant advertising campaign in Greece.
Methods: We reviewed the medical records of the patients with RM seen at the ENT outpatient clinic in May, June and July of 2003 and 2006. We analyzed and recorded the gender, age, and related clinical information of the patients with RM.
Results: In May, June and July of 2003, 41 patients out of a total of 1780 patients attending the ENT outpatient clinic were diagnosed with RM (2.3%). In the same months in 2006, 161 patients out a total of 1898 patients were diagnosed with RM (8.5%). The frequency of RM in these groups was therefore found to have increased significantly between 2003 and 2006. In 2006, 8 out of 10 patients with RM reported that they had made their purchasing decision solely on the basis of the information supplied by the drug advertisement without consulting their doctor or pharmacist.
Conclusion: We suggest that the intensive media advertising campaign for nasal topical decongestants (particularly on TV) which started in 2004 is probably the main reason for this "endemic" RM.

Abbreviations

RM: Rhinitis Medicamentosa
EPOS: European Position Paper on Rhinosinusitis and Nasal Polyps
ENT: Ear-Nose-Throat
CT: Computer Tomography
RAST: Radioallergosorbent Test

Introduction

Rhinitis medicamentosa (RM) is a syndrome involving rebound nasal congestion caused by the overuse or misuse of topical nasal vasoconstrictive decongestants. In the EPOS consensus, RM is classified as a condition associated with the use of intranasal decongestants involving atrophy of the nasal mucosa.[1] These medications fall into two general classes: the sympathomimetic amines such as ephedrine or phenylephrine (short-acting agents) and imidazoles, including oxymetazoline and xylometazoline (long-acting agents).[2] RM typically occurs after 5-7 days of medication use. Long-acting agents are less likely to cause rebound swelling than short-acting decongestants and they can be used for periods of more than 5 days. This means that RM can also appear later in cases of prolonged use.[2]

Many conditions require the use of nasal decongestants. However, it is important to elicit the reason for the use of vasoconstrictive medication. As the patient continues using these agents, tachyphylaxis occurs, resulting in increased frequency of use and shorter duration of action.[3] RM was recognised as a distinct nosologic entity in 1946 and the term was coined by Lake.[4] Ryan[5] presented the related histopathology in 1947. RM is a drug-induced, non-allergic form of rhinitis, in which inflammation of the nasal mucosa is induced or aggravated by the excessive or improper use of topical decongestants.[6,7]

The effect of drug advertising through TV, radio, magazines and newspapers is well known. The drugs that are promoted achieve high sales within months. Unfortunately, few patients read warning leaflets and the information provided is frequently poor. The aim of this study was to investigate the frequency of RM in May, June and July of 2003 and 2006 in order to assess possible differences between these two periods, since an escalation of media advertising for nasal decongestants was in progress.

Patients and methods

This study included all patients seen at the ENT outpatient clinic of the General Hospital of Rethymnon (Crete, Greece) in May, June and July of 2003 and 2006. We reviewed the medical records of patients with RM attending the ENT outpatient clinic of the General Hospital of Rethymnon (Crete, Greece) in May, June and July of 2003 and 2006. Gender, age, nasal disorders and the frequency of RM were recorded. We analysed medical history and, whenever necessary, laboratory tests. The management of all cases was studied. Otorhinolaryngologists performed the RM diagnosis and treatment.

The diagnosis of RM is generally established when there is persistent and prominent nasal congestion following the use of intranasal decongestants on a daily basis for more than two weeks.[8] The characteristic mucosal changes, plus a poor response to local sympathomimetic agents, are also required to establish a convincing diagnosis of RM.[9] Flexible endoscopy with and without local anaesthesia plus vasoconstriction was also available as a routine diagnostic option. Depending on medical history, CT scans and/or RAST tests were used in some cases to define the cause of the initial nasal obstruction.

Empirical estimates that there was a progressive rise in the frequency of RM during 2004 and 2005 led to the introduction of questionnaires at the ENT outpatient clinic in 2006 in order to collect supplementary information. When RM was diagnosed, this short questionnaire was useful in acquiring further information about decongestant use (Figure 1). Data was obtained about the duration and frequency of patient use of local nasal decongestants, as well as the effect of advertising on decongestant purchasing. Descriptive statistical analysis took place. Contingency tables and chi-square testing were used to compare the data, such as the frequency of RM in two different time periods.

This study was approved by the local ethics committee.

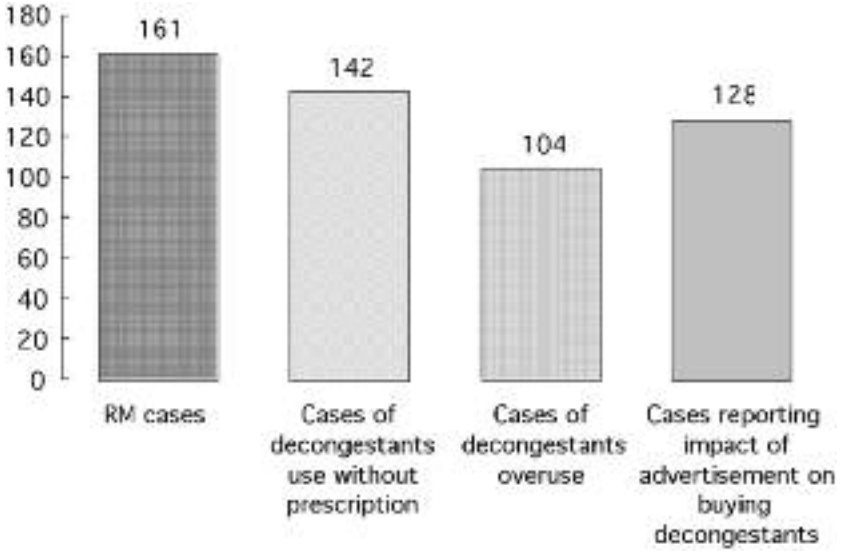

Figure 1
RM cases and reported information about decongestant use (analysis of 2006 RM cases).

Results

There were 41 patients (group A) with a diagnosis of RM out of a total of 1780 patients attending the ENT outpatient clinic (2.3%) in May, June and July of 2003. 161 patients (group B) out of a total of 1898 patients (8.5%) were diagnosed with RM during May, June and July of 2006. The frequency of RM diagnosis was found to have increased significantly between 2003 and 2006 groups (from 2.3% to 8.5%, chi-square = 66.753, $p < 0.001$). The median age of the patients was 47 years (limits: 22-80 years) in group A and 43 years (limits: 18-83 years) in group B. There were 20 males and 21 females in group A, and 77 males and 84 females in group B. In our group B patients, the related nasal disorders we found were: allergic rhinitis (n = 43), upper respiratory infection (n = 36), nasal polyposis (n = 20), vasomotor rhinitis (n = 15), chronic rhinosinusitis (n = 17), more than one condition (n = 18). No cause was identified in twelve cases. According to our study, 142 out of 161 patients in group B (88.2%) reported nasal decongestant use without a prescription and 104 patients (64.6%) had abused this over-the-counter medication, using it for longer than one month. Moreover, the vast majority of the patients (128/161, 79.5%) reported that they had made their purchasing decision solely on the basis of the information supplied by the advertising without consulting their doctor or pharmacist.

Details about the related underlying nasal disorders were not available for group A. In addition, there were no data about the frequency of use of the local nasal decongestants without a prescription for group A (in 2003).

Discussion

We found a threefold increase in RM diagnosis between 2003 and 2006. Looking for the causes of this "endemic" RM, we believe the main reason is likely to be the direct-to-consumer advertising for nasal decongestants in Greece which started in 2004. Greek law encourages people to assume greater responsibility for their own care, and prescription medicines such as nasal decongestants are increasingly available over the counter. Consumers usually acquire information about their home remedies through advertising, friends and relatives, physicians, pharmacists and product labels. By far the most influential of these is advertising and much concern has been voiced about consumers' unquestioning faith in drug advertising.[10] In our study, 8 out of 10 patients reported that they based their purchasing decision solely on the information supplied by the drug advertising without consulting their doctor or pharmacist. Unfortunately, the quality of information in drug advertisements is frequently poor and misleading. These advertisements often exaggerate a drug's benefit while downplaying its hazards, urging people to bypass doctors and treat themselves.

RM is a iatrogenic condition with a specific background, clinical features and therapeutic approach. This condition is more frequently encountered in young and middle-aged adults than in children and elderly patients; gender incidence appears to be the same in male and female patients.[2,11] In our study, frequence was slightly higher in females. The main symptom of patients with RM is chronic nasal congestion, especially at night, punctuated by temporary periods of relief following the use of the nasal decongestant spray. If this condition is left untreated, severe nasal blockage can lead to oral breathing and to a dry, sore throat, which may in turn cause insomnia, snoring and disturbed sleep.[12] Clinical features of RM include inflammation of the mucosa with oedema, erythema, dryness and multiple punctate bleeding sites. As a rule, the nasal mucous membrane appears congested in these patients. "Beefy" red and granular but pale, oedematous and boggy variants have also been described.[13] In a later stage, the mucous membrane becomes atrophic and crusted.[11] Key issues in the treatment of RM include the discontinuation of decongestant use, the functional re-establishment of the nasal airway, and the correction of any underlying defect.[9] In addition, the withdrawal process in our patients was facilitated by using topical corticosteroids.[14] The treatment of RM also includes the combination of antihistamine with pseudoephedrine per os. We used corticosteroid nasal sprays, mainly mometasone fuorate and budesonide, but more occasionally fluticazone propionate, in the patients from group B. In 25 patients, we also used corticosteroids per os (methylprednisolone) and in 35 patients with allergic rhinitis we also prescribed antihistamines (desloratadine or levocetirizine).[15] It can therefore be deduced that the overall approach to RM is more complex and demanding than thought. Consumers need reliable and objective information about the use of nasal decongestants so they can avoid possibly harmful effects of iatrogenic origin. Since a ban on drug advertising is not possible and the effects of the advertising on public health merit further discussion, some preventive measures are required. Pharmaceutical companies should inform people fully about their products through the patient information leaflets. All essential instructions about usage, potential side-effects and contraindications must be clearly listed in the medication leaflet.

The study by Bell *et al*.[16] indicates that a substantial proportion of people incorrectly believe that only the safest and most effective drugs are advertised directly to consumers. In addition, the study by Davis[17] has shown that consumers rate the safety and appeal of drugs more positively when risks are not fully stated than when the risks are described better. Unfortunately, the information that pharmaceutical industries supply directly to patients is usually more promotional than objective, possibly as a result of companies' marketing plans. For example, although direct-to-consumer advertising is banned in the Netherlands, two cases have already gone to court, where it was pointed out that the "disease awareness" campaigns crossed the "grey" line into advertising and promotion to the detriment of objectivity and public education.[18] Additionally, in the USA, where a law prohibiting direct-to-consumer advertising has never been passed, it has already been

suggested that drug advertising has influenced health care spending by pushing up the number of prescriptions per person and demand for newer and more expensive drugs.[18]

It has been reported that one out of three general practitioners prescribe typical decongestants in allergic rhinitis as a first-line approach.[19] It is crucial to inform patients fully about the benefits, risks and alternatives of the prescribed medication. In the case of patients without a prescription, a comprehensive interaction between consumers and pharmacists about how to select the most appropriate medicine, as well as about drug risks and benefits, is also imperative. When a medicine with pharmacy status is sold, the pharmacist should supervise its sale.[10] Nasal decongestants should be used for no more than seven days in a row, and preferably only at the lowest concentration, and when nasal congestion is most bothersome. The use of nasal decongestants should then be stopped completely.[6] If symptoms persist, a complete assessment is mandatory before using a nasal decongestant for a longer period of time. The patient should be referred by the general practitioner or advised by the pharmacist to see an ENT specialist so that the aetiology of the nasal obstruction can be identified.

Conclusion

In conclusion, RM is a common and underestimated condition which is best managed by prevention. Further prospective studies need to be carried out in order to confirm these findings as well as to assess the underlying factors, which, in Greece are related to improper drug use or abuse.

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