






Minor ailment service for dry eye syndromes: I-VALOR programme

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KEYWORDS

Pharmaceutical Services, Minor Ailment Service, Community Pharmacies, Dry Eye Syndromes

ABBREVIATIONS

ADRs: Adverse drug reactions
CP: Community pharmacies
DES: Dry Eye Syndromes
GP: General practitioner
HP: Health problem
MAS: Minor Ailment Service
PhS: Pharmaceutical Service
RC: Referral criteria
TFOS: Tear Film and Ocular Surface Society

ABSTRACT

Background: Minor ailment service offered in community pharmacist is a key element in patient care. Thought in Spain the service is not properly documented.

Aims: The main objective was to evaluate community pharmacists' interventions through an agreed minor ailment service for dry eye syndromes (DES).

Method: Descriptive study undertaken alongside I-VALOR programme (January-June 2015). Participants were pharmacists from SEFAC who voluntarily decided to do, and patients were those who consulted about DES in community pharmacy.

Pharmacists used the Pharmaceutical Care Forum guideline for the Minor Ailment Service and an agreed consensus between pharmaceutical and medical societies. A patient's form and a referral's form were designed.

Results: There were 6,350 patients involved. 62.7% consultations were made by women (24.3% of 46-65 years old). No referral criteria were detected in 60% of patients. The pharmacist detected 3,887 referral criteria in 2,537 patients. Pharmacists decided not to refer 15.4% of those patients. 87.3% of the patients referred accepted the referral. Treatments were dispensed in 80% of patients: 3,157 pharmacological treatment (89.2% a single medication) and 2,403 non-pharmacological treatment (medical device, food supplement or eye cleaning product). 35% received hygienic-dietary advice and pharmaceutical advice. Twenty-five adverse drug reactions were detected (0.4%). 70.5% of all consultations made were managed with no referral to a general practitioner (GP).

Conclusions: I-VALOR programme allowed to evaluate an agreed intervention for DES in community pharmacy through the record of MAS to demonstrate CP contribution to manage minor ailments.

Introduction

Minor Ailment Service (MAS) is probably the most demanded service in community pharmacy (CP) after dispensing medicines. Some studies about MAS have shown that this service represents around 10-17% of the total professional actions performed in the CP (1,2). This Pharmaceutical Service (PhS) is provided

upon patient request in the pharmacy, when unsure of which medicinal product to acquire and upon requesting that the pharmacist provides the most appropriate remedy for a specific health problem. If the service requires the dispensing of a medicinal product, it shall be carried out in accordance with the Dispensing Service (3).

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Minor ailments are defined as “common or self-limiting or uncomplicated condition that may be managed without medical (i.e. GP intervention, that may not have relation with other health problems suffered by the patient, nor with the effects, desired or not, of the medicines taken by the patient, which therefore respond or are alleviated with symptomatic treatment” (4).

The professional work of the community pharmacist in MAS is very important as the first line of assistance to the population. However, it is not sufficiently valued due to the lack of records and the almost non-existent issuance of referral reports. It is an activity that entails a high responsibility on the part of the professional (5) who puts all his knowledge into improving patient's health. I-VALOR (6) programme was designed to encourage standard operational procedures in MAS and to promote specific records (referral and patient forms). In the first phase of the programme, standard operational procedures were agreed for five minor symptoms: heartburn, minor upper respiratory symptoms, skin erosions, allergies and dry eye syndrome.

Dry eye syndromes (DES), according to the Tear and Film & Ocular Surface Society's (TFOS) second dry eye workshop (DEWS II) (7), is a “multifactorial eye surface disease, characterised by a loss of homeostasis of the tear film, accompanied by ocular symptoms, in which instability of the tear film, hyperosmolarity, inflammation, damage to the ocular surface and neurosensory anomalies play etiological roles”.

The prevalence of DES is variable depending on the diagnostic criteria and the population studied (7). If symptoms appearance is taken into account, said prevalence ranges from 5 to 50%; however, if it is only based on signs, it reaches up to 75% in some populations. Global prevalence estimation is limited by the fact that there are hardly any studies in populations under 40 years old or in the southern hemisphere (8). Risk factors identified as consistent remain as defined in the previous TFOS report (9): age, race, Meibomian gland dysfunction, connective tissue disease, Sjögren's syndrome, androgen deficit, computer use, contact lenses use, oestrogen

replacement therapy, haematopoietic stem cell transplantation, certain environmental conditions (such as pollution, low humidity and sick-building syndrome) and the use of medication (antihistamines, antidepressants, anxiolytics, isotretinoin, etc.).

DES treatment aims to restore the homeostasis of the eye surface and the tear film (10). For the treatment of the initial stages of the disease, community pharmacists, in accordance with Royal Legislative Decree 1/2015 (11), may indicate non-prescription medicines of the therapeutics groups S01XA, V0126, V0136, 13000, 13A01 and 13A02 Anatomical Therapeutic Chemical (ATC Classification System).

To perform MAS in an adequate manner, community pharmacists must be trained in the pathology, diagnosis, treatment, and referral criteria (RC) to other healthcare professionals (12).

The main objective of this paper, which is part of the I-VALOR programme, was to describe community pharmacists' interventions through MAS when facing a consultation about DES using protocols. In addition, the following specific objectives were established:

- To promote MAS records in CP: referral form to another healthcare professional and patient's form.
- To quantify the consultations managed without referring the patient to the general practitioner (GP).

Material and methods

Design and duration of the study

Descriptive, observational study carried out between January and June 2015, within the I-VALOR programme (6).

Study population

Community pharmacists who voluntarily decided to participate in the study. Community pharmacists did not receive any compensation for participating.

Procedure

Community pharmacists in the study received five-hour online training on MAS for DES and the registration system.

Patients considered in the study were those who came to the CP requesting a remedy to alleviate the symptoms of DES.

When a patient consulted about dry eye in CP, MAS was performed and data was collected on a platform enabled for this purpose.

To provide the service, I-VALOR programme (6) methodology was followed, which included the procedure for MAS established by the Pharmaceutical Care Forum in CP (3) and the standard operational procedures for DES previously agreed upon by the scientific societies SEFAC (Spanish Society of Clinical, Family and Community Pharmacy), SEMERGEN (Spanish Society of Primary Care Physicians) and semFYC (Spanish Society of Family and Community Medicine). These procedures included RC which are signs and symptoms whose presence indicates that the pharmacist should refer the patient to the GP for evaluation (Figure 1) (13). In addition, a referral form, a patient form and the DES recommendation sheet were used.

Study variables

The variables collected were:

Patients' characteristics

- Sex: independent categorical variable (Male/Female).
- Age: independent polychotomous variable with 5 categories (<18/18-30/31-45/46-65/>65).
- Who made the consultation: independent polychotomous variable with 3 categories that refers to the person who consults in the CP (Patient/Caregiver/Other).
- The patient takes another medication: independent categorical variable (Yes/No).

Pharmacist's intervention

- RC detected: dependent polychotomous variable with 12 categories.
- Referrals to other health professionals: dependent categorical variable (Yes/No).
- Acceptance of referral by patient: dependent categorical variable (Yes/No).
- No. of medicines dispensed: number of packs of medicines dispensed to patients. Dependent polychotomous variable (0/1/2/3).

- Type of active substance dispensed: dependent polychotomous variable with 13 categories.
- Type of non-pharmacological treatments dispensed: medical devices, food supplements, eye cleaning products or other products recommended by the pharmacist. Dependent polychotomous variable.

- Type of adverse drug reactions (ADR) detected: dependent polychotomous variable.

Ethical aspects

Patient data was collected anonymously. The study was classified by the Spanish Agency of Medicines and

Medical Devices (AEMPS) as EPA-OD (Other post-authorisation observational studies) and approved by the Research Ethics Committee of the Centre of Granada (CEI-GRANADA). Community pharmacists signed a participation form and patients signed an informed consent form prior to their inclusion.

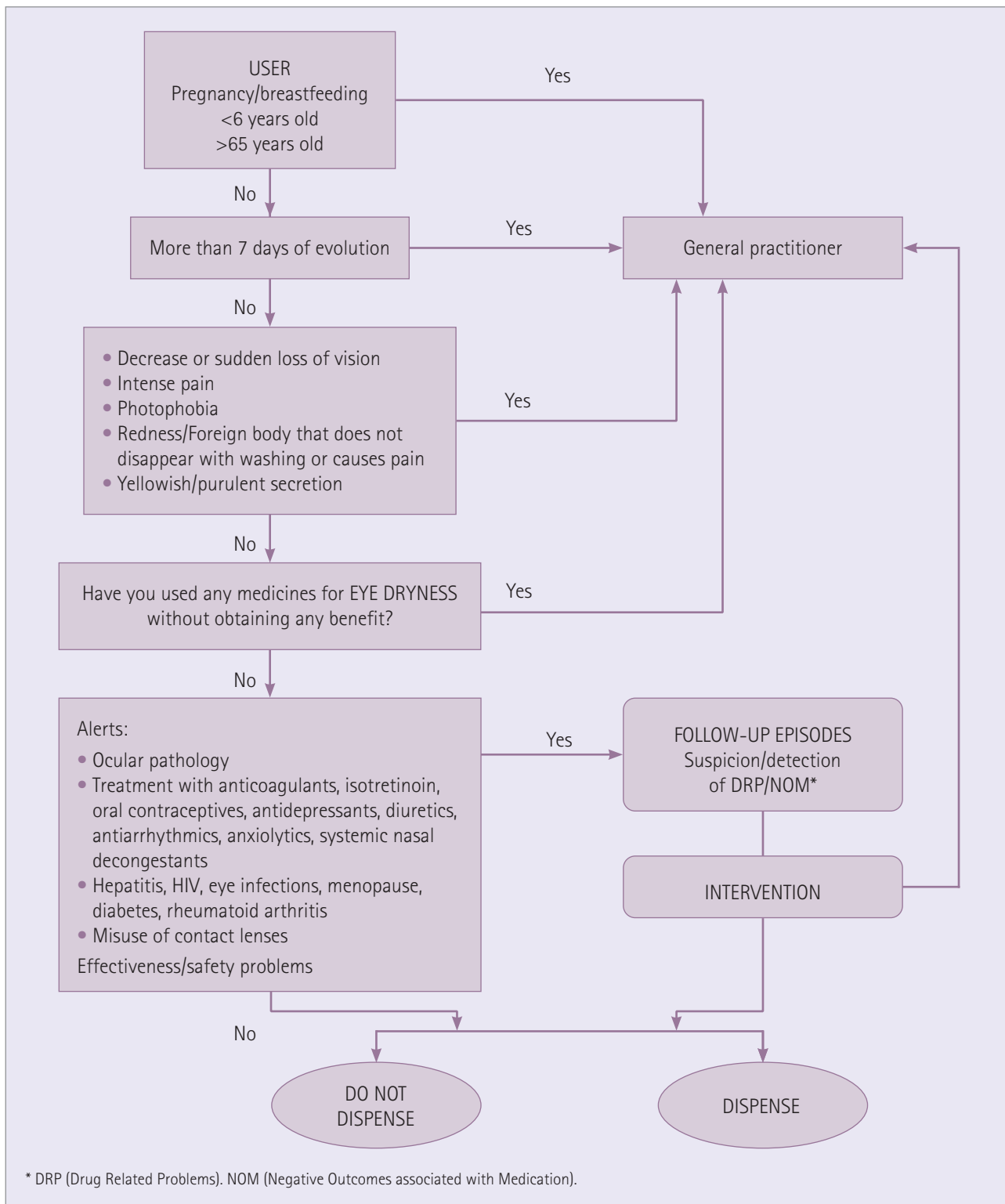


Figure 1 Minor Ailment Service Procedure for Dry Eye Syndromes (13)

Statistical analysis

A descriptive analysis of the variables collected was performed. All the variables collected were categorical and therefore expressed in frequencies and percentages. For the comparison of the variables, the Pearson test χ^2 was used, establishing the statistically significant differences when $p < 0.05$. Microsoft Excel 2013 program was used.

Results

I-VALOR programme involved 1,022 community pharmacists working in 846 CP in all the provinces of Spain, their characteristics are detailed in the paper by Salar et al (6). 37,701 records were made with an average of 36.9 cases per pharmacist (SD=24.8) and 44.5 cases per CP (SD=37.5). Of these, 6,350 records were due to DES, which represented 16.8%, recorded by 768 pharmacists with an average of 8.2 cases (SD=3.3), maximum of 32 and minimum of 1 record.

Most DES consultations, 62.8% (n=3,990), were made by women. The age group with the highest number of consultations was between 46 and 65 years old (35.4%, n=2,248), of which 1,543 (24.3%) were women. 87.1% (n=5,533) of the consultations were made by the patient himself. 51.7% (n=3,624) of the patients were taking medicines for other health problems (Table 1).

RC were not detected in 3,813 (60%) patients, 1,602 (25.2%) patients

had only one RC and 935 (14.7%) patients had two or more RC.

A total of 3,887 RC were detected, among which the following stood out: age (20.8%, n=809), contact lenses use (12.4%, n=483), pain, photophobia, redness (11.1%, n=430) and the appearance of secretions (11.0%, n=426) (Figure 2).

RC were detected in 2,537 patients, of which 390 (15.4%) patients were not referred to other health professional by community pharmacists (Table 2). Of the 2,147 patients who were advised to go to the GP or the emergency room, 272 (12.7%) refused the referral, hence, 1,875 patients (29.5% of total consultations) were referred and accepted the referral. No statistically significant differences were found in referrals according to sex, but there were statistically significant differences in referrals by age ($p < 0.05$).

Among patients who refused referral, the most frequent RC were: 26.3% (n=83) due to contact lenses use, 15.5% (n=20) due to hormonal problems, 13.0% (n=91) due to age over 65 years old and 10.8% (n=29) with symptoms lasting more than 7 days (Table 2). Patients accepted being referred in most cases when RC were: chronic ocular pathology (95.4%, n=167), presence of secretions (94.9%, n=387) and adverse reactions to topical drugs (94.7%, n=54) (Table 2).

Another community pharmacist's action in MAS was the recommendation of a non-prescription medicine.

Table 1 Characterisation of patients treated at MAS in DES (N=6350)

	n (%)
Sex	
Male	2,360 (37.2%)
Female	3,990 (62.8%)
Age (years)	
<18	174 (2.7%)
18-30	913 (14.4%)
31-45	1,430 (22.5%)
46-65	2,248 (35.4%)
>65	1,585 (25.0%)
Who makes the consultation?	
Patient	5,533 (87.1%)
Caregiver	615 (9.7%)
Other	202 (3.2%)
Patient takes other medication	
Yes	3,624 (57.1%)
No	2,726 (42.9%)

MAS: minor ailment service; DES: dry eye syndromes.

A total of 3,157 non-prescription medicines were recommended to 2,984 patients (47.0%), of which 2,815 (94.3%) received one medicine, 165 (5.3%) received two medicines and 4 (0.1%) received three medicines (Table 3). Most patients who receive a non-prescription medicine did not have any RC. Table 4 describes the type of patient and the number of medicines dispensed by type. 81.0% (n=1518) of patients who accepted the referral were not given any medicines.

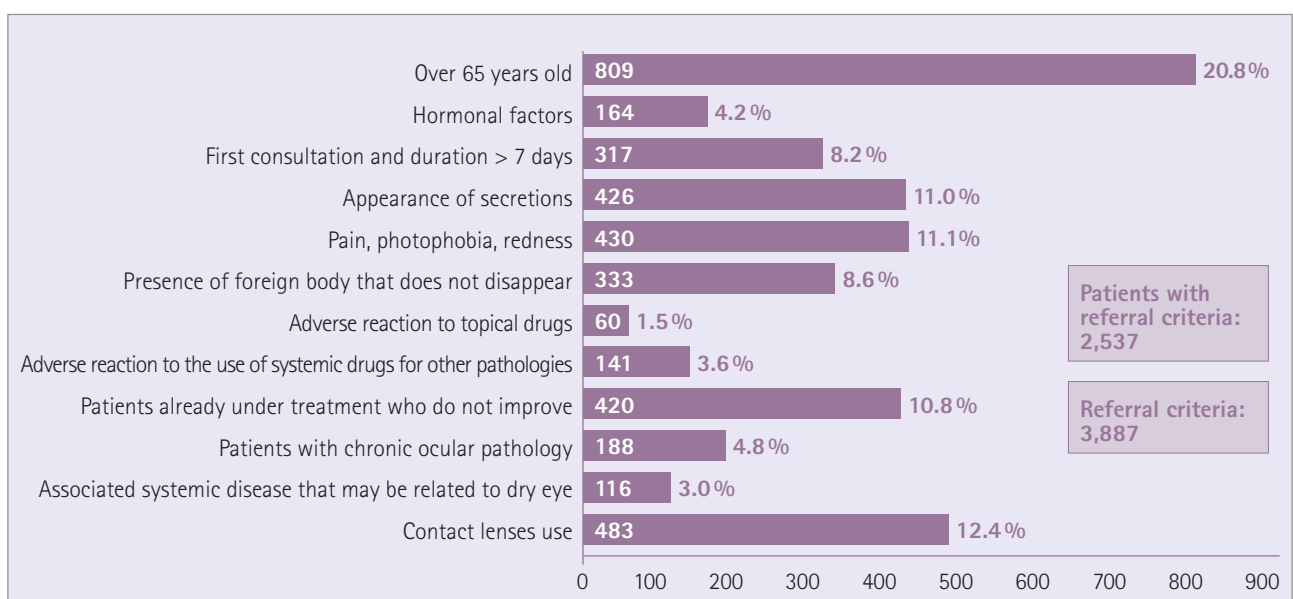


Figure 2 Referral criteria in patients



Table 2 Patients with RC who are referred and accept/reject the referral

	No. RC	Referral		Acceptance of referral	
		No	Yes	No	Yes
Over 65 years old	809	109 (13.5%)	700 (86.5%)	91 (3%)	609 (87%)
Hormonal factors	164	35 (21.3%)	129 (78.4%)	20 (15.5%)	109 (84.5%)
First consultation and duration > 7 days	317	49 (15.5%)	268 (84.5%)	29 (10.8%)	239 (89.2%)
Appearance of secretions	426	18 (4.2%)	408 (95.8%)	21 (5.1%)	387 (94.9%)
Pain, photophobia and redness	430	22 (5.1%)	408 (94.9%)	25 (6.1%)	383 (93.9%)
Presence of foreign body that does not disappear	333	30 (9%)	303 (91%)	22 (7.3%)	281 (92.7%)
Adverse reaction to topical drugs	60	3 (5%)	57 (95%)	3 (5.3%)	54 (94.7%)
Adverse reaction to the use of systemic drugs for other pathologies	141	16 (11.4%)	125 (88.6%)	12 (9.6%)	113 (90.4%)
Patients already under treatment who do not improve	420	19 (4.5%)	401 (95.5%)	35 (8.7%)	366 (91.3%)
Patients with chronic ocular pathology	188	13 (7%)	175 (93%)	8 (4.6%)	167 (95.4%)
Associated systemic disease that may be related to dry eye	116	7 (6%)	109 (94%)	8 (7.4%)	101 (92.6%)
Use of contact lenses	483	168 (34.8%)	315 (65.2%)	83 (26.4%)	232 (73.6%)
Total RC	3,887	489 (12.6%)	3,398 (87.4%)	357 (10.5%)	304 (89.5%)
Total patients with RC	2,537	390 (15.4%)	2,147 (84.6%)	272 (12.7%)	1,875 (87.3%)

RC: referral criteria.

Table 3 Number of medicines and other products dispensed to patients

No. of products dispensed per patient	No. of patients on medication, n (%)	No. of patients with medical devices, food supplements or eye cleaning products, n (%)
1	2,815 (94.3%)	1,807 (86%)
2	165 (5.6%)	262 (12.5%)
3	4 (0.1%)	30 (1.5%)
Total	2,984 (100%)	2,099 (100%)

Table 4 Number of medicines dispensed to patients

Patient characteristics	No. of medicines dispensed			
	0	1	2	3
Patients who have no referral criteria	1,569	2,153	91	0
Patients who are chosen not to be referred	169	201	19	1
Patients who do not accept the referral	110	140	22	0
Patients who accept the referral	1,518	321	33	3

The active ingredients of the medicines dispensed (therapeutic group ATC S01XA) are included in **Table 5**, the majority being hypromellose (31.7%).

2,099 patients received non-pharmacological treatment: medical devices

from groups 13A00, 13A01 and 13A02, food supplements of groups V0126 and V0136, cleaning products and other eye care products. A total of 2,403 non-pharmacological treatments were recommended: 1,685 (70.1%) medical devices, 94 (3.9%)

of food supplements, 545 (22.7%) of cleaning products and 79 (3.3%) of other products.

Non-pharmacological treatment was recommended to 86% of the patients (n=1,807), 12.5% (n=262) received two and 1.5% (n=30) received three (**Table 3**). Of the 1,685 medical devices recommended, hyaluronic acid was the most common treatment (1,089; 64.6%), followed by propylene glycol/hydroxypropylguar (258; 15.3%), polyvinylpyrrolidone/actinoquinol (66; 3.9%) and sodium chloride (52; 3%).

Healthy lifestyles and/or hygienic-dietary measures were offered in 35% of the consultations (n=2,224). 19.9% of the total number of consultations (n=1,267) only received these kinds of recommendations, without pharmacological or non-pharmacological treatment.

70.5% (n=4,475) of all consultations made were managed without the need for a referral.

25 ADRs (0.4%) were detected due to the use of medicines that could have dryness of the eye as adverse effect, which were reported

Table 5 Active ingredients dispensed

Active ingredients (group S01XA)	No. of packages dispensed, n (%)
Hypromellose	997 (31.7%)
Carmelosa	363 (11.6%)
Hamammelis	325 (10.3%)
Carbomer	275 (8.7%)
Carbomer/Benzalkonium chloride	273 (8.6%)
Polyvinyl alcohol/Benzalkonium chloride	244 (7.7%)
Sodium chloride	145 (4.6%)
Vaseline	98 (3.1%)
Hypromellose/Dextran/Benzalkonium Chloride	75 (2.4%)
Hypromellose/Sodium Chloride/Benzalkonium Chloride	64 (2.0%)
Polyvinyl alcohol/Polyvidone	39 (1.2%)
Vaseline/Lanolin/Paraffin	30 (0.9%)
Others	229 (7.2%)
Total	3,157 (100%)

to pharmacovigilance through www.notificaram.es which connects with the Spanish Centre for Pharmacovigilance.

Discussion

This study applies referral criteria agreed with GP in a MAS. The programme also allows the generation of a semi-automatic referral form to facilitate the communication between health care professionals.

It is known that minor symptoms are resolved in CP through MAS (14,15,16). The I-VALOR programme allowed to record 37,701 consultations for 5 minor symptoms (heartburn, allergies, skin erosions, dry eyes and cold), 16.8% of which were due to dry eyes. In Spain, the DES prevalence is estimated to be around 11% (17), however, in CP there are studies that have calculated a prevalence of 4.3% (18) although the sample size is limited. International studies have calculated a prevalence of eye problems in CP between 9.7% and 10.3% (19), these studies also included other health problems such as conjunctivitis in addition to dry eye.

The percentage of women included in this study is similar to the results obtained in other studies and ranged from 60-66% (20,21,22). The fact that in most cases was the patient who made the consultation and patients' age (46-65 years old) were also similar to that obtained in other studies (22).

Among the possible interventions of the pharmacist in MAS were referral to the GP, selecting a pharmacological treatment, non-pharmacological treatment or healthy lifestyles. Regarding the referrals made in the study, 29.5% of referrals were made to the primary care and emergency room. This is like the percentage obtained in the same study when all the minor symptoms studied were taken into account, 29% (23). In addition, there are other studies on MAS in which fewer patients were referred, between 2.4-7.4% (24,25). This difference could suggest a possible selection bias since, as the I-VALOR programme promoted the record of MAS emphasizing those cases that had to be referred to the GP, community pharmacists may not have recorded all cases in which the recommendation was different from referral to the GP.

Treatment was given to 80.1% of patients, compared to 89% found in similar later studies (25). It should be noted that in most cases only one medicine was dispensed, with significantly fewer recommendations for two or more medicines. In addition, the percentage of patients who were neither dispensed nor referred to another health professional (19.9%), that is to say, the percentage of patients who were recommended to modify their lifestyles, was similar to that obtained in other studies (21). In Spain, community pharmacists do not receive any payment for

MAS consultation. All this shows the health-focused approach projected by most community pharmacists since a high percentage symptom was managed without dispensing or with only one product dispensed.

The study has shown that community pharmacists have an important role as health agents in the management of patients with minor symptoms, in this case DES.

With all of this, the need to use standard operational procedures in CP has been highlighted in this study, underlining the importance of achieving consensus for RC with other health agents represented in pharmaceutical and medical scientific societies.

Limitations of the study

Among the limitations of the study was the lack of randomisation of patients although similar patients' characteristics to other studies were obtained. For future studies, it would be necessary to evaluate consultations' outcomes on patients. On the other hand, the inclusion of patients at risk of suffering health problems other than a minor symptom, might have resulted in the high referral rate (differential selection bias).

Conclusions

The I-VALOR programme has allowed to reflect the pharmacist's intervention, as the electronic record demonstrates with real and numerical data the work carried out from the CP.

Most consultations were managed at the CP without the need to refer to the GP, selecting a pharmacological nor non-pharmacological treatment.

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