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## PHARMACEUTICAL CARE AND CLINICAL MONITORING OF THE ALLERGIC PATIENT: A CASE REPORT

### ATENÇÃO FARMACÊUTICA E MONITORAMENTO CLÍNICO DO PACIENTE ALÉRGICO: RELATO DE CASO

### ATENCIÓN FARMACÉUTICA Y MONITORIZACIÓN CLÍNICA DEL PACIENTE ALÉRGICO: RELATO DE CASO

#### ABSTRACT

**Objective:** This paper aimed to verify the impact of the clinical monitoring of an allergic patient associated to Pharmaceutical Care (PC) in his quality of life.

**Methodology:** The patient was assessed through respiratory flux evolution, skin-prick test, blood count and nasal fluid analysis associated to the St. George Hospital questionnaire about respiratory diseases and a clinical interview. A symptoms chart was used for patient's self-management. Domiciliary visits were made for reviewing compliance.

**Results:** Specific interventions were used for providing effective pharmacotherapy. The St. George Hospital questionnaire score of impacts decreased 76% from the first to the last consultation. The patient had an improvement of 59% and 50% on expiratory and inspiratory fluxes rate, respectively.

**Conclusions:** A positive prognostic was seen, suggesting that the methodology can be used for allergic adult patients PC services.

**Descriptors:** Allergies, Clinical Monitoring, Pharmaceutical Care, Pharmacotherapy.

#### RESUMO

**Objetivo:** Verificar o impacto do monitoramento clínico associado ao método TOM de Atenção Farmacêutica na qualidade de vida de um paciente alérgico.

**Metodologia:** O paciente foi avaliado através de testes respiratórios, Prick Test, leucograma e lavagem nasal, associados à uma anamnese farmacêutica e ao questionário sobre doenças respiratórias do St George Hospital. Foram feitas visitas domiciliares e foi fornecido ao paciente um diário para o monitoramento dos sintomas.

**Resultados:** Intervenções específicas foram feitas para proporcionar uma farmacoterapia eficaz. O escore de impactos do questionário do St George Hospital reduziu 76% entre a primeira e a última consulta. Ao fim do monitoramento, o paciente apresentou melhora de 59% e 50% nos fluxos expiratório e inspiratório, respectivamente.

**Conclusão:** O paciente apresentou prognóstico positivo, sugerindo que a metodologia pode ser empregada para pacientes alérgicos adultos.

#### RESUMEN

**Objetivo:** El objetivo de este estudio fue verificar el impacto de la monitorización clínica de un paciente alérgico asociadas a la atención farmacéutica en su calidad de vida.

**Métodos:** El paciente fue evaluado através del análisis del flujo respiratorio, prueba de punción cutánea, leucograma y análisis del líquido nasal asociada al cuestionario del St. George Hospital, de enfermedades respiratorias, y a una entrevista clínica. Se utilizó un diagrama de los síntomas para la monitorización clínica del paciente en casa. Visitas domiciliarias se realizaron para verificar el cumplimiento del tratamiento.

**Resultados:** Intervenciones específicas fueron utilizadas para proporcionar un tratamiento farmacológico eficaz. El cuestionario del St. George Hospital hay presentado impacto reducido de 76% desde la primera hasta la última consulta. El paciente tuvo una mejora de 59% y 50% en los flujos espiratorios y de inspiración, respectivamente.

**Conclusiones:** Un pronóstico positivo se ha visto, que sugiere que la metodología puede ser utilizada para servicios de atención farmacéutica a pacientes adultos alérgicos.

**Descriptor:** Alergias, monitorización clínica, atención farmacéutica, farmacoterapia.

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## INTRODUCTION

Type one hypersensitivity or allergies are characterized by high production of immunoglobulin E (IgE) for low antigen levels, generally harmless for major of the population, inducing local or generalized inflammatory processes, which tend to become stronger with ageing<sup>(1)</sup>. The immunopathology of allergies results from atopy, the genetic susceptibility to type one hypersensitivity, involving an unbalance of T<sub>H</sub>1 and T<sub>H</sub>2 lymphocytes pathway activation, release of T<sub>H</sub>2 cytokines like IL-4 and IL-13, activation, recruitment and degranulation of basophils and mast cells, tissue eosinophilia and mucus hypersecretion<sup>(2-4)</sup>.

The incidence of allergic diseases has increased all over the world in the last decades reaching about 20%, and the number of allergens is steadily increasing<sup>(5,6)</sup>. Currently, Brazil is among the countries of higher prevalence rates of allergic rhinitis and asthma<sup>(7)</sup>. The hygiene hypothesis, which states that the development of polarized T<sub>H</sub>2 responses is due to low exposure to the environment and infectious diseases, has been the most used explanation in the clinical context for these high rates<sup>(4,9)</sup>.

There have been extensive efforts to develop clinical guidelines for allergies treatments<sup>(5)</sup>. Dietary, environmental, and genetic factors can influence allergy outcomes, and their investigation can help to establish personalized prevention strategies<sup>(4,5)</sup>. Current treatments involve allergens avoidance, immunotherapy, health education and drug therapy, the most employed option. However, clinical alternatives have been required because not all of the patients respond to normal therapy, thus, the pharmacist's involvement is essential for ensuring an optimized and safe drug therapy<sup>(6,9)</sup>.

Pharmaceutical Care (PC) is the pharmacist direct provision of drug-related care by health education, in order to improve patients' quality of life when using medication<sup>(10)</sup>. In the clinical context, PC becomes an essential health care service for achieving definitive therapeutics outcomes through preventing or solving drug related problems (DRP)<sup>(11)</sup>.

This case-study aimed to verify the impact of the association of PC to the clinical monitoring of an allergic patient, comparing his clinical picture before and after the pharmaceutical interventions. Our results indicate that the implemented measures are effective in improving patients' outcomes in allergic diseases. Few studies have investigated drug therapy for allergic conditions, and, to our knowledge, this is the first time that PC interventions in respiratory allergies are described.

## METHODOLOGY

Ethical approval was obtained from Centro Universitário do Leste de Minas Gerais Ethics Committee prior to commencement of this study (protocol 16.88.08). A patient with previous allergy diagnosis, registered at Respirar sem Fronteiras program<sup>12</sup> with frequent problems related to medication usage and strong allergic clinical complaints, was kindly invited to begin a PC follow-up in our study. The follow-up had a total duration of 8 months.

## PC PROCEDURES

Once there was no specific PC follow-up for allergies published, and PC is carried out for one patient each time, the case-study strategies were selected for a better assessment of the whole methodology used in the research. PC was performed through the Therapeutic Outcomes Monitoring (TOM) methodology<sup>10</sup>, world-wide used for chronic diseases, allied to allergies clinical monitoring, a sub-service of PC developed for this study.

## CASE DESCRIPTION

M.M.S., a 26-year-old man, with early allergy diagnosis and history of strong allergy symptoms since 12 years old. In the first consultation, the patient presented typical allergic shiners and chronic nasal unilateral obstruction with transversal furrow on the right nostril. The patient reported sensitivity and responsiveness to cold air, quick oscillations of home temperature and air humidity, cats and dogs, tobacco smoke and mites. The most frequent problems described by him during the allergic

crisis were rhinitis symptoms (itchy and runny nose, sneezing and watery eyes), chest tightness, ocular pruritus and nocturnal sibilance.

The physician prescribed budesonide (32mcg/dose) for nasal instillation during the crisis and chlorpheniramine combined to phenylephrine and acetaminophen in industrialized capsules (4/4/400mg/dose), for reducing the allergies symptoms, mainly rhinitis and itching. The patient stopped using his medication two months before beginning the follow-up, relating inefficacy of both and complaining about sleepiness.

## AMBULATORIAL FOLLOW-UP

The clinical monitoring was performed by in monthly ambulatorial consultations through a complete blood count exam, respiratory flow, skin-prick test and "bolus" method of nasal fluid analysis<sup>(13)</sup>, in a total of eight consultations.

The respiratory flow was assessed in each consultation: three measurements were made in orthostatic position, using both In-Check (Clement Clarke) and Peak Flow (Clement Clarke) portable nasal flow meters. Previously to the readings being taken, the patient received appropriate instructions on how to use the meters correctly and was supervised while readings were obtained<sup>14</sup>.

The prick test (FDA Allergenic) was performed according to the manufacturer's instructions in the first consultation, using the following antigens: mites, cat, dog, cockroach, air fungus and grass, with positive and negative controls (Table 1).

Size	Reaction	Visual Characteristics
0	Negative	Presence only in the point of inoculation
+ /4	Weak	Wheals: about 3mm
++ /4	Medium	Wheals from 3 to 5mm
+++ /4	Strong	Wheals from 5 to 9mm
++++ /4	Intense	Wheals bigger than 9mm with pseudopodia

Table 1 Skin-prick Test references values

A clinical interview was developed for the pharmaceutical anamnesis and used associated to the St. George Hospital questionnaire about respiratory diseases<sup>(16,17)</sup>. Health education about allergies was provided to the patient during the whole treatment for improving his quality of life.

## DOMICILIARY FOLLOW-UP

The domiciliary follow up strategies were based in the statements of the American Society of Health-System Pharmacists<sup>(18)</sup>. These visits aimed to assess therapy compliance defining necessary interventions, environment control measures compliance and the current clinical picture<sup>(19)</sup>. The frequency was weekly, being gradually reduced to monthly, in a total of 14 visits. Information about the correct usage of medicines and the current clinical picture were collected through the questionnaires and the patient's and his family's reports.

A daily chart of allergies control (Table 5) was developed for this study. This instrument was used by the patient to report the frequency of symptoms all over the treatment, stimulating the self-management of the disease. The following protocol was used: a blank chart was given to the patient in each ambulatorial consultation after instructions were presented. In the next consultation, it was changed for a blank one and analyzed with the patient, in order to make clear his clinical picture and involve him in the clinical decisions, an important issue in PC practice.

The options of this chart were chosen according to the patient's needs and specific guidelines<sup>20,21</sup>, for providing a better analysis of the clinical outcomes and the pharmaceutical interventions.

## RESULTS AND DISCUSSION

### Laboratorial Tests and Respiratory Flow

We aimed to show immunological indication of allergies beyond clinical signs and symptoms, thus, the exams of this section were

performed on the beginning of the follow up. The complete blood count showed eosinophilia and basophilia, and the nasal fluid analysis showed eosinophilia. Basophils are suggestive of acute allergies reaction, and eosinophils are suggestive of chronic picture of allergies<sup>2,20</sup>.

It has been described that the eosinophil cationic protein is able to disrupt the upper airways epithelial coverage integrity, what may help to explain some of the clinical symptoms, considering also the presence of allergies inflammatory mediators like histamine and leukotriens, whom plays important roles in the immunoregulation of acute and chronic allergic inflammation<sup>(1-5,21)</sup>.

All the antigens used in the Prick Test triggered strong reaction on the patient's skin (Table 2), what gave us more direction for selecting the best interventions for health education for allergen avoidance and drug therapy.

Antigen	Size of Wheal (in mm)
Mites	9
Air Fungus	7
Dog	5
Cat	8
Grass	9
Cockroach	6

Table 2 Prick Test Results

Allied to pharmacotherapy, simple respiratory exercises were suggested in the first consultation for breathing improvement, with physical therapist supervision. The patient's respiratory flow improvement is shown in table 3:

Consultation	Peak Flow	In check
1	345	50
2	405	65
3	450	70
4	480	70
5	490	75
6	510	75
7	530	70
8	550	75

Table 3 Respiratory Evolution in l/min

### PC Procedures and Ambulatorial Follow-up

Based on TOM classification of DRPs, the DRP#7 was identified (i.e. poor compliance): the patient was administrating the medication incorrectly, during the moment of crisis but not at the first symptoms, and two months before the treatment began, he decided not to take them anymore.

It is well established that due to the slow onset action of chronic medications, patients may question their value, and once they gain certain experience on the medication usage because of their body response, the correct way to take the medication may be altered<sup>(14,22,23)</sup>.

Strategies for identifying the first symptoms and for allergen-avoidance were presented, like the removal of carpets and curtain, daily cleaning of fans, windows and the bedroom's floor and furniture, and weekly change of bed and bath trousseaus.

The patient's care plan included health education for the correct usage of medicines. The sedative effects of chlorpheniramine and the preventive aspects of allergies pharmacotherapy were explained to the patient, and he was advised to visit the clinician for substituting this medicine. On the patient's request and also our recommendations, the physician substituted the capsules for loratadine combined to pseudoephedrine in tablets.

The St. George Hospital questionnaire about respiratory diseases that assess their impacts in an individual's life was used in the follow up.

Even though it is generally used for COPD patients<sup>17</sup>, this instrument was not used aiming clinical significance for this work, but some direction of conclusion. In addition, the analyzed patient showed strong influence of allergies in his respiratory performance, what influenced the choice for this questionnaire. The maximum scores reference values were extracted from the 2003 instruction manual.

All the questionnaire results had a strong decrease, indicating the reduction of the frequency and intensity of the symptoms, confirming the results obtained in the daily chart of allergies control. From the first to the last consultation, the symptoms score reduced 82,8%, the activity score (shows the influence of allergies in daily life activities) reduced 71,4%, the impacts score (shows the psycho-social influence of allergies) reduced 65,2% and the total score reduced 76,2%. The results are presented in table 4:

Consultation	Symptoms Score RV = 15	Activity Score RV = 12	Impacts Scores RV = 2	Total Score RV = 7
1	72,03	48,57	53,90	55,29
2	61,42	41,55	31,12	39,31
3	61,29	18,16	27,50	30,28
4	55,28	12,26	21,93	24,54
5	17,54	23,74	34,77	28,57
6	15,15	18,21	25,42	17,82
7	14,42	16,31	22,05	15,44
8	12,37	13,90	18,78	13,16

Table 4 Results from the SGHQ by each consultation. RV = reference values

The daily chart of allergies symptoms (Table 5) was mainly used to stimulate the patient to use the self-monitoring strategies for allergy symptoms, which were explained through health education measures during the consultations and domiciliary visits. The symptoms frequency reduction suggests the clinical evolution of the patient.

Month	1	2	3	4	5	6	7	8
Cough	16	9	4	4	3	0	1	0
Sibilance/ Breathlessness	14	9	2	3	4	0	0	0
Chest Tightness	10	5	0	0	0	0	0	0
Rhinitis	22	15	9	11	11	5	4	4
Nasal/Ocular Itching	15	6	3	3	5	3	3	2

Table 5 Evolution of Signs and Symptoms in Number of Monthly Occurrences

## CONCLUSION

This study provided data supporting the positive prognostic of allergies when clinical monitoring strategies are associated to PC, a successful association described by the first time. The clinical parameters evolution, the quality of life improvements and the patient's financial resources savings are the main results of this work, what suggest the effectiveness of the measures implemented in the treatment. The regular meetings and domiciliary visits, focused in the knowledge of the disease and oriented for improving therapeutics results, pharmacotherapeutic monitoring and environmental control measures usage, created a communication network, an essential item for identifying and solving DRP.

Reduction of the severity of signs and symptoms, clinical complaints, use of medicines and of the number of medical consultations was shown, and the cost of the treatment, considering only medication and consultations, reduced 40% on the end of the follow-up, according to the patient's calculus.

Our observations suggest strategies for pharmacological intervention

on the immune system, and the employment of world-wide used methods improved the plausibility of our findings. However, due to the nature of the sample and proceedings, it is hard to ensure the generalisability of the results for other groups of patients but young adults. Thus, further validation will be required to provide representative and significant data from the statistical point of view on the usefulness of the methodology here presented on PC to allergic patients.

This limitation, however, has no implication on our measuring of the responsiveness of the instruments used in this study, as the relate more to the ability of PC to influence in the quality of life.

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## REFERENCES

1. Traid-Hoffmann C, Jaakob T, Behrendt H. Determinants of Allergenicity. *J Allergy Clin Immunol*, 2009; (1) 1-9.
2. Gould HJ, et al. The Biology of IgE and the Basis of Allergic Disease. *Annu Rev Immunol*, 2003; (21): 579-628.
3. Pawankar R. Inflammatory Mechanisms in Allergic Rhinitis. *Curr Opin Allergy Clin Immunol*, 2007; (7): 1-4.
4. Bordignon V, Burastero SE. Age, Gender and Reactivity to Allergens Independently Influence Skin reactivity to Histamine. *J Invest Allergol Clin Immunol*, 2006; 2(16): 129-135.
5. Scadding GK, et al. BSACI guidelines for the management of allergic and non-allergic rhinitis. *Clin Exp Allergy*, 2008; (38): 19-42.
6. Hashizume M, Takigawa M. Anxiety in Allergy and Atopic Dermatitis. *Curr Opin Allergy Clin Immunol*, 2006; (6): 335-339.
7. Asher MI, et al. Worldwide time trends in the prevalence of symptoms of asthma, allergic rhinoconjunctivitis, and eczema in childhood: ISAAC Phases One and Three repeat multicountry cross-sectional surveys. *Lancet*. 2007; 368 (9537): 733-43.
8. Hansen I, et al. Mediators of inflammation in the early and the late phase of allergic rhinitis. *Curr Opin Allergy Clin Immunol*, 2004; (4): 159-163.
9. Bisgaard H, et al. Childhood asthma after bacterial colonization of the airway in neonates. *N Engl J Med* 2007; (357): 1487-1495.
10. Hepler, CD. Pharmaceutical Care. *Pharm. World Sci*, 1996; 18 (6): 233-236.
11. Hepler CD, Strand LM. Opportunities and Responsibilities in Pharmaceutical Care. *Am J Hosp Pharm*, 1990; 47(3): 533-543.
12. DIAS-SOUZA, M.V., Santos, A, OLIVEIRA, F. M. Clinical Evolution of the Patients Followed up by Respirar Sem Fronteiras Program - UNILESTE-MG In: XXXII Congress of the Brazilian Society for Immunology - II Extra Section of Clinical Immunology, 2008, Ribeirão Preto. *Annals of the XXXII Congress of the Brazilian Society for Immunology - II Extra Section of Clinical Immunology*, 2008.
13. Caminha GP, et al. Lavagem Nasal como Método de Avaliação das Cavidades Nasais. *Rev Bras Otorrinolaringol*, 2001; 6 (67): 859-862.
14. Peters SP, et al. Tiotropium Bromide Step Up Therapy for Adults with Uncontrolled Asthma. *N Eng J Med*, 2010; (363): 1715-1726
15. Antunes J, et al. Skin Prick Tests and Allergy Diagnosis. *Allergol Immunopathol*, 2009; 37 (3): 155-164.
16. Jones PW, Quirck FH, Bavestock CM. The St George's Hospital Respiratory Questionnaire. *Respir Med*, 1995; 85 (Suppl B): 25-31.
17. Ferrer M, et al. Interpretation of Quality of Life Scores from the St George's Hospital Questionnaire. *Eur Respir J*, 2002; (19): 405-413
18. American Society of Health-System Pharmacists. ASHP guidelines on the pharmacist's role in home care. *Am J Health-Sys Pharm*, 2000; (57): 1250-1255.
19. Bhattacharya D, et al. Pharmacist domiciliary visiting in England: identifying the characteristics associated with continuation. *Pharm World Sci*, 2008; (30): 9-16.
20. Mandhane SN, Shah JH, Thennati R. Allergic Rhinitis: An Update on Disease, Present Treatments and Future Prospects. *Int Immunopharmacol*, 2011; (11): 1646-1662.
21. Dykewicz MS, Hamilos DL. Rhinitis and Sinusitis. *J Allergy Clin Immunol*, 2010; 125 (2): S103-S115
22. Shoemaker S, Ramalho de Oliveira D. Understanding the meaning of medications for patients: The medication experience. *Pharm World Sci*, 2008; (30): 86-91.
23. Smith L, et al. Treating asthma with a self-management model of illness behaviour in an Australian community pharmacy setting. *Social Science & Medicine*, 2007; (64): 1501-1511.