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Evaluation of patients' satisfaction with domiciliary biological treatment in severe asthma: a Portuguese survey

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Dear Editor,

According to GINA [1], severe asthma is defined as uncontrolled asthma, despite therapy adherence with an optimized high dose of inhaled corticosteroid plus long-acting ß2-agonist coupled with management of modifiable factors/comorbidities, that worsens when this treatment is decreased. It affects a significant portion of asthmatic patients and imposes a high risk of exacerbations and mortality, which are associated with significant healthcare costs and psychosocial impact.

The emergence of biological agents (monoclonal antibodies) has provided promising targeted therapy for severe asthma in recent past years, leading to improved asthma control, fewer exacerbations and enhanced quality of life [2]. Although traditionally administered in a hospital setting, most of them had received recent approval for at-home administration. This possibility has been supported by previous safety and efficacy studies, especially when preceded by thorough supervised training by a healthcare professional, similarly to other treatments such as insulin [2]. However, the self-administration of subcutaneous medication outside of a supervised environment can raise certain concerns. Nevertheless, available data suggests that the risk of serious adverse effects from biological agents in severe asthma is small (0.1-0.2% anaphylaxis) and the simplicity of prefilled syringes/auto-injectors minimizes the likelihood of critical errors [3].

Despite being an increasingly common practice in many centers, there is a noticeable gap in the literature concerning patients' perspectives in real-life settings. Therefore, our aim was to evaluate, for the first time in Portugal, the satisfaction with at-home biological treatment in severe asthma patients.

For this purpose, a 15-question survey was developed in portuguese language, covering the following domains: demographics, description of at-home therapy, prior hospital-based training, experienced adverse effects, satisfaction, main advantages/concerns, willingness to maintain at-home self-administration and recommendations for supportive tools. All patients followed at our center (Pneumology or Immunoallergology appointments) for severe asthma and prescribed with biological therapy for at-home administration, were included. Enrollment occurred between April to August 2022, during routine hospital visits. Informed consent was signed by the participants.

Thirty patients underwent biological treatment for severe asthma: 19 (63.3%) received at-home treatment, while the remaining used hospital administration (therefore excluded). The survey response rate was 94.7% (18 patients included). Patients were mainly female (15, 83.3%), with a mean age of 54±10 years. Regarding professional occupation: 10 (55.6%) were employed, 7 (38.9%) pensioners and 1 (5.6%) unemployed. Eleven patients (61.1%) used mepolizumab and 7 (38.9%) used benralizumab. The median time performing at-home administration was 15.7 months (9.9-17.3).

As for the survey results (Table 1), previous self-administration training in a hospital environment was unanimously considered adequate (18, 100.0%). However, 2 patients expressed a desire to receive a regular review of the administration technique by a healthcare professional. Timesaving was the main advantage for the at-home regimen (15, 83.3%), generally 1-5 hours per treatment. Other reported benefits included, minimal disruption in work/family routine, flexible administration schedule and reduced risk of a hospital acquired infection.

Most patients (10, 55.6%) did not experience any adverse effect. Nevertheless, some reported fatigue/sleepiness (n=3), joint pain (n=2), local skin reactions (n=1), headaches (n=1) and hair loss (n=1) during the initial administrations. Thirteen patients (72.2%) expressed no apprehension with this regimen. However, the possibility of experiencing adverse effects without immediate evaluation and the concern of doing critical errors in the administration technique were reported by 2 patients, respectively. Overall, fifteen patients (83.3%) were very satisfied with at-home administration and all 18 patients expressed the desire to maintain this modality.

Our study reported real-world evidence of the positive patient's perspective regarding at-home administration of biological agents for severe asthma in a Portuguese center. The majority were

satisfied/very satisfied with the at-home regimen and timesaving was stated as the primary advantage. Furthermore, no significant adverse effects were reported. These results suggest that at-home administration can be a valid therapeutical option in carefully selected and previously trained patients.

Regarding patient selection, Flokstra-de Blok and colleagues highlighted key features for a successful transition to domiciliary treatment, such as an assessment of anaphylactic risk, clear instructions/training including initial supervised self-injection, direct pathway to contact healthcare professionals, regular medical monitoring and social support [4]. Despite rare, anaphylaxis is an issue for healthcare professionals to implement this regimen. Major knowledge regarding anaphylaxis in biologics stems from the omalizumab and reslizumab pivotal studies, as only case reports/series have been published for the others [3]. It seems more frequent in females, people with previous anaphylactic reaction (polysorbates, food, drugs, others) and during the first hours after the first three administrations. To mitigate the risk, a recent task force recommends, especially in patients with preceding history of anaphylaxis, education on the signs/symptoms of anaphylaxis; prescription of an epinephrine auto-injector and higher post surveillance times [3,4].

Understanding the patient's perspective is now a central feature when implementing a novel drug administration regimen, in parallel with its efficacy and safety which were addressed in previous studies [2]. The benefits of this regimen appear to be convenience and cost-effectiveness, through flexible schedules that avoid work absences and less need of long-distance travels to the hospital. Additionally, the willingness to maintain this therapeutical modality was unanimous in our sample. As patients become more independent in the management of their disease, timesaving for healthcare professionals and reduction in treatment-related expenses are expected.

The main limitation of this study consist in its small sample and the fact that only mepolizumab/benralizumab were used. That relies on the fact that no pre-filled syringes were available for omalizumab and dupilumab, the latter recently approved for asthma treatment in Portugal. Furthermore, it was a single-center study, which does not allow for extrapolation to other environments.

Nonetheless, our study is one of the few to address patients' opinions/perspectives in biological self-administration. Patient reported outcomes are gaining increasing relevance not only in clinical trials but also on everyday clinical practice.

In conclusion, our results emphasize the satisfaction of severe asthmatic patients with at-home self-administration of biological drugs, an aspect that should be considered in our clinical practice. Larger multicenter and multinational studies, with extended follow-up, are needed to

corroborate and provide greater external validity, by including a variety of cultural backgrounds that could affect the personal perception of treatment.

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Table 1. Questions (extracted from the survey) related to personal perspective/experience regarding the at-home biological treatment and the respective multiple-choice answers.

Question	Answers – n (%)
Regarding the control of the symptoms that led to the initiation of biological medication, how satisfied are you?	Very satisfied - 10 (55.6%) Satisfied - 7 (38.9%) Unsatisfied - 1 (5.6%)
Do you consider the prior training for home administration of biological medication to be sufficient/adequate?	Yes - 18 (100%)
Would you like more explanatory support in the form of:	No additional support required - 15 (83.3%) Regular review of administration technique by healthcare professionals - 2 (11.1%) Demonstrative videos - 1 (5.6%)
What is the primary advantage of home-based administration of biological treatment compared to administration at the hospital?	Time saving per treatment - 15 (83.3%) Minimal impact on daily routine (e.g. work absences) - 1 (5.6%) Lower infection risk (COVID-19, hospital-acquired bacteria, etc.) - 1 (5.6%) Treatment flexibility (e.g., schedule) - 1 (5.6%)
On average, how many hours do you estimate you save with each home-based biological treatment administration compared to hospital administration?	1-5 hours - 15 (83.3%) Less than 1 hour - 2 (11.1%) More than 5 hours - 1 (5.6%)
Have you experienced any of the following adverse effects associated with biological medication? Check all that apply.	No adverse effects - 10 (55.6%) Fatigue/sleepiness - 3 (16.7%) Joint pain - 2 (11.1%) Skin changes at the administration site (e.g., redness, warmth, swelling) - 1 (5.6%) Headache - 1 (5.6%) Hair loss - 1 (5.6%)
What is your primary concern regarding home-based administration of biological treatment?	None - 13 (72.2%) Errors in drug injection - 2 (11.1%) Undesirable/adverse effects without immediate evaluation by a healthcare professional - 2 (11.1%) Forgetting to take the medication - 2 (11.1%)
How satisfied are you with the home-based biological treatment regimen?	Very satisfied - 15 (83.3%) Satisfied - 3 (16.7%)
Regarding the administration of biological treatment, if possible, would you prefer to:	Continue the home-based treatment regimen – 18 (100%)