
*Brief Communication***Severe Asthma, Telemedicine, Self-administered therapy: listening first to the patient****Gabriella Guarnieri¹, Marco Caminati², Alessia Achille¹, Rachele Vaia³, Fulvia Chieco Bianchi¹,****Gianenrico Senna^{2,3}, Andrea Vianello¹**

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Abstract: Severe asthma patients are at increased risk of major exacerbations and they need to be monitored regularly. The COVID-19 pandemic has impressively impacted on the health care resources. The telemedicine approach applied to the follow-up of asthmatic patients has been proved to be effective in monitoring their disease and adherence to the therapy. The aim of our study was to investigate the satisfaction of severe asthma patients, before the activation of a telemedicine management complemented by a standard of care. An *ad hoc* questionnaire was developed and sent by e-mail to 180 severe asthma patients. Most of subjects (82%) were confident with the idea of doing self-measurements and self-managing their disease; 77% of subjects favoured to carry out virtual visit and telemedicine. 93% of patients considered easy the self-injection therapy. 94% of subjects felt safe and 93% were not worried while self-administering. Only mild adverse events were reported in 22% subjects after self-administration. Our results showed an agreement between what is considered necessary and practicable by healthcare personnel and what is perceived by the severe asthma patients, in terms of treatment and monitoring of the disease with Telehealth. Biologics have a safety profile and can be easily self-administered at home.

Keywords: patient empowerment; home-administration; patient preferences; adherence; biologics

Introduction

Severe asthma patients are at increased risk of major and frequent exacerbations, emergency room and hospital admission; therefore they need appropriate pharmacological treatment to be tapered according to disease control [1,2]. The COVID - 19 pandemic has impressively impacted on the health care resources, and the restrictions to in person-visits has widely

promoted the use of telemedicine in several chronic conditions, including bronchial asthma [3]. According to the results of previous studies the telemedicine approach applied to the follow-up of asthmatic patients has been proved to be effective in reducing respiratory symptoms and improving their quality of life [4,5]. Another study described a similar disease control in patients managed by the use of telemedicine or by the conventional face-to-face visits suggesting telemedicine as an effective tool for home-monitoring [6]. Telemedicine may be reliable for the management of asthma at any level of severity. In fact, besides the home spirometry and the digital visits, the adherence to the therapy can be easily monitored [7]. Severe asthma patients, besides pandemic restrictions, were regularly tele-monitored for their home self-administered biologic therapy [8]. However, the recent development of inhaler trackers assessing the real-time usage of inhaled drugs may represent a step forward in achieving a better adherence to asthma treatment at any level of severity. The patients' empowering, which represents a crucial step for achieving an optimal asthma control, can be considerably implemented by e-health technologies and telemedicine, included the availability of digital apps providing warning notifications [9,10]. The patient's perception and judgement about the management of their disease through telemedicine tools represents an underestimated issue. In fact, telehealth (i.e., virtual consultation) does exclude the physical interaction between patients and health care professionals thus reducing the usual emotional contact. However, patient satisfaction with self-administration of biologics in severe asthma has been reported [11,12].

The aim of our study was to investigate in a group of severe asthma patients the aptitudes and satisfaction of telemedicine tools and the self-administration of injection therapy before the activation of a telemedicine management complemented by a standard of care.

Methods

AN *ad hoc* questionnaire was developed by the physicians operating in the severe asthma referral Centers participating to the study (Padua and Verona, north east of Italy) and sent by e-mail to the patients, in order to investigate both the satisfaction of telemedicine tools and the self-administration of injection therapy. The questionnaire consisted of 13 items, each one of them to be rated from 0 to 4, according to grade of satisfaction, where 0 is "extremely", 1 "very much", 2 "moderately" 3 "a little", 4 "not at all" satisfied. The first item was about the self-assessment of breathing, oxygen saturation, state of health at home and patient empowerment; the second one was about the patient's ability with technology, the third regarded the proposal to make a virtual visit. The fourth question investigated whether the patient perceived to be properly followed-up by the doctor with telemedicine management, the fifth explored whether the patient preferred the standard in person visit instead of the virtual one. The other eight questions were related to self-injection therapy at home, in particular to the evaluation of how easy was the injection procedure (sixth) and syringe or injector (tenth), safety and skill (seventh), feeling un-anxious (eighth), any adverse events after injection (ninth). The eleventh question was whether the patient would recommend it to another severe asthma patient, if training was clear (twelfth) and the last one investigated if the patient's choice was conditioned by the COVID-19 pandemic.

Results

The questionnaire was sent to 180 severe asthma patients regularly treated by two allergy and respiratory referral centers for severe asthma located in the North-east of Italy (Verona and Padua), on biologic treatment. Overall 167 subjects (93%) completed the questionnaires. The study population consisted of 54% females, with an average age of 55 ± 13 (mean \pm SD) years, under the following biologic treatment: 37% Mepolizumab, 28% Omalizumab, 31% Benralizumab and 4% Dupilumab. All answers to the questionnaire are summarized on the table 1. Most of subjects (82%) were confident with the idea of doing self-measurements and self-managing their disease (31% extremely), whereas 7% disliked this at all (figure 1A). In the study population 77% of subjects favoured to carry out virtual visit and telemedicine, and in the same percentage they felt adequately followed by doctors; however, 72% have preferred the conventional standard visits in the clinic. In our study most of patients were on average skilled with technology, being only 5% completely unable. Almost all patients (93%) considered easy enough the self-injection therapy (52% extremely) as well as easy to use the auto-injector device (94%). We did not observe differences in the positive judgment among patients between syringe and auto-injector therapy, when clustering the patients according to the type of biologic. Most of patients (94%) felt safe (50% extremely, 31 % very much and 13% moderately) and 93% were not worried while self-administering, feeling only 1% of subjects insecure and anxious. Some symptoms were reported by 22% of patients within the 2-3 days following self-administration (figure 1B). When requested to detail those symptoms, they were the following: small bruises at the injection site (34%), mild headache in the evening of administration (45%) and in the remaining cases fatigue were reported. Therefore, only mild adverse events were reported, which subside without therapy. With the exception of 3% of patients, all would recommend self-administration (54% extremely). The training performed for the self-administration at the clinic was rated as satisfactory by almost all patients (66% extremely, 31 very much, 2% moderately, 1% not at all). Patient's choice was not conditioned by the COVID-19 pandemic in 51% of case, while in 19% and 13% extremely and very much respectively.

Discussion

It is frequently observed that what is considered by the physician to be useful and clinically significant for the patient does not correspond to the actual and perceived need of the patients themselves. This can result in a low therapeutic adherence or even a poor professional-patient relationship [13]. During the COVID-19 pandemic, every effort was carried out to prevent a possible infection in patients affected by severe chronic respiratory diseases such as severe asthma. Specific pathways have been identified to allow patients to receive appropriate medical care and to carry on the biological therapies, thus preventing the lack of disease control as well as acute severe exacerbations [3-10]. Up to now, as far as we know, no investigations have been carried out among the severe asthma patients to evaluate their perspective about the telemedicine approach. Our results showed an agreement between what is considered necessary and practicable by healthcare personnel and what is appreciated and perceived by the patients affected by severe asthma, in terms of treatment and monitoring of the disease with Telehealth. The severe asthma patient is used to frequent medical visits, to

take a great amount of drugs (needing to be often modulated in terms of dose and frequency), to experience exacerbations. The healthcare personnel-patient relationship is therefore very close. However, we found that training for self-administration therapy, self-measurements breathing and for conducting virtual visits was effective, highly appreciated by patients and strengthened the patient's empowerment. Overall our patients enjoyed telemedicine very much and did not feel abandoned in the context of the telemedicine approach. The biologics used for severe asthma are equipped with handy injectors, which were considered to be very easy by the patients themselves. Though biological treatments can be considered more "invasive" than tablets, they were self-administered without anxiety by most of our patients. Biologics in severe asthma, as known from the literature, are overall safe [14]. Our data also confirm their safety profile, in fact more than two out of three among our patients did not experience any adverse events after self-administration, and in the other cases they experienced common and mild symptoms. The Covid-19 pandemic has affected almost half of our patient's choice to join telemedicine and the biologics self-administration. Also in this aspect an agreement emerged between healthcare personnel and patients for safety issues and to keep the severe asthmatic patients monitored. Following the overall technological evolution in the field of Medicine, it is very likely that telemedicine revolution would have characterized our way of practicing in a few years but it is undeniable that Covid-19 pandemic significantly fastened the process. The small sample size represents a major limitation of this study. However, patients were representative of the North-east Italian population, also considering the low prevalence of severe asthma. The questionnaires were completed in the absence of the investigator. This eliminated the possibility of bias from the investigator, however, this could have led to misunderstanding of certain, not so comprehensible questions.

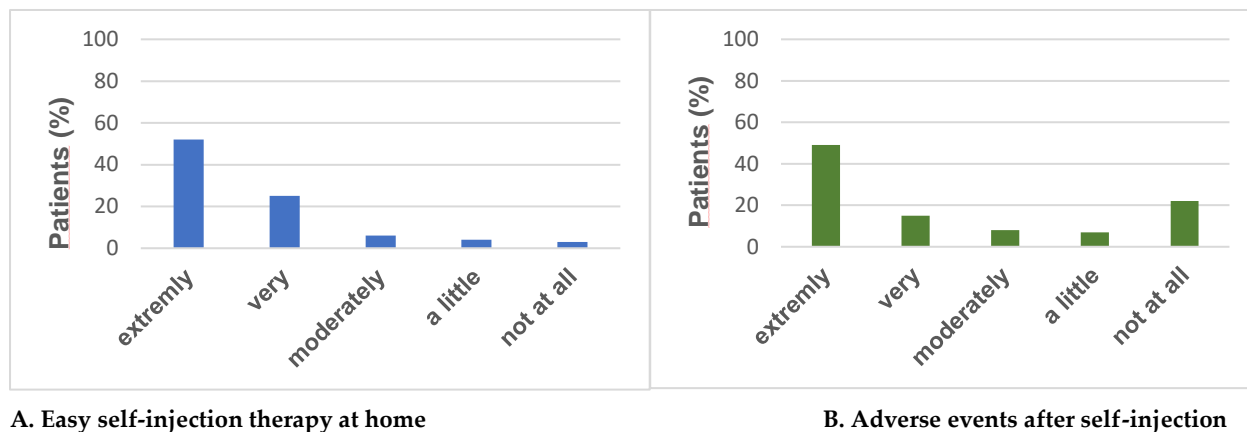
Conclusion

Our data, according to severe asthmatics report, suggest to extend telemedicine in routine clinical practice to other asthmatic patients and in general to patients with chronic respiratory diseases. Finally, high treatment satisfaction with one's medication would encourage adherence in clinical practice. For the patients not satisfied with the telemedicine approach, the benefit of biologics needs to be re-assessed. Further research in the field may include the re-administration of the same questionnaire, to be compared with the previous results, in order to include the telemedicine management as a precision medicine tool.

Table 1: Patient perception and satisfaction of Telemedicine tools and self-administration of injection therapy

Items		Extremely (% patients)	Very much (% patients)	Moderately (% patients)	A little (% patients)	Not at all (% patients)
1	self-assessment of breathing and oxygen saturation, patient empowerment	31	25	26	11	7
2	patient's ability with technology	27	28	28	12	5

3	satisfaction to make a virtual visit	30	27	20	16	7
4	perception to be properly followed-up by the doctor with telemedicine management	21	24	31	15	9
5	preference in person <i>versus</i> virtual visit	21	28	23	19	9
6	easy self-injection therapy at home	52	25	16	4	3
7	safety and skill about the injection procedure	50	31	13	5	1
8	feeling un-anxious	50	25	18	6	1
9	adverse events after self-injection	49	15	8	7	22
10	easy syringe or injector	60	27	7	0	6
11	recommendation to another severe asthma patient about self-injection	54	32	10	1	3
12	clear training at Clinic	66	31	2	0	1
13	patient's choice conditioned by the COVID-19 pandemic	19	13	17	17	34

Figure 1: Perspective, Agreement and Safety of Self-administred Biologics: answers of severe asthma patients

Author Contributions: Conceptualization: G.G., S.E.; Methodology: G.G., S.E., V.A.; Formal Analysis: G.G., S.E., C.M.; Investigation: G.G., C.B.F., V.R., Data Curation: G.G., A.A., V.R.; Writing: G.G., S.E., C.M.; Original Draft Preparation: G.G.; Writing—Review and Editing: G.G. All authors agree to be accountable for all aspects of the work.

Funding: This research did not receive any supporting funds

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of Verona University Hospital (3930/AO/16).

Informed Consent Statement: Informed consent was obtained from all of the subjects involved in the study.

Conflicts of Interest: No potential conflict of interest was reported by all the authors.

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