

The Effects of the COVID-19 Lockdown on Severe Asthma in Patients Taking Biologic Therapy and Air Pollution in Riyadh

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Abstract

Background:

The curfews and lockdowns imposed during the COVID 19 pandemic may decreased volume of traffic and reduced air pollution. In addition, social distancing measures may contribute to reduce infection and asthma exacerbation.

Objective:

To assess asthma control and asthma medication use among sever asthmatics on biologics before and after COVID-19 pandemic

Method:

This is a cross-sectional survey study of patients with severe asthma receiving biologic therapy at King Abdulaziz Medical City-Riyadh (KAMC-R), Saudi Arabia. We looked at the effects of the COVID19 lockdown on this cohort of sever asthmatics on biologic therapy from March till June 2020 over a period of 12 weeks. We investigated changes in patients symptoms and asthma control using the asthma control test (ACT) score and other parameters including, emergency department (ED) visits, hospitalizations, use of oral prednisolone, changes in inhaler therapy, frequency of bronchodilators use and patient perception of their symptoms before and after the lockdown period.

Results:

A total of 56, Female 39;(69%0; mean age \pm SD 47.4 \pm 13.8 years. The duration of bronchial asthma since diagnosis range from 4-30 years. Most patients had been treated with Omalizumab (47; 84%); the rest received Mepolizumab (7; 12.5%) and Dupilumab (2; 3.6%). All these patients had been on biologic therapy for 5 months, range from 5 to 120 months. Most of the patients (45; 80.4%) agreed that their symptoms of asthma had improved with biologic therapy. Most of the patients felt overall asthma symptoms is better after curfew and lockdown 28 (50%). Less use of bronchodilators post curfew reported in 38% of the patients. Asthma control (≥ 20) using ACT score was significantly higher among patients in post curfew and lockdown period compared to pre curfew period 34(61.7%) and 23 (41%), (p.0.001) respectively.

Conclusion: Asthma control was better post curfew and lockdown. Decrease in air pollution and social distances may be contribute factor.

Introduction

Asthma is a chronic inflammatory condition of the airways that results in variable bronchial hyperresponsiveness and airflow limitations causing symptoms.(1) Recent data suggests that around 650 million people live with some degree of asthma symptoms worldwide.(2) Hospitalization and

medications are the most important associated direct costs, while work and school absenteeism account for the greatest percentage of indirect costs.(3,4)

Patients die from asthma.[5] Yet, whilst Coronavirus Disease 2019 (COVID-19) wreaked havoc, and the world re-evaluated every aspect of contemporary life taken for granted in 2019; an expected increase in exacerbations of asthma did not materialize. The explanation for this clearly important observation is unclear.

The curfews and lockdowns imposed during the COVID 19 pandemic may have prevented transmission of other infections besides Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2). Furthermore, the decreased volume of traffic and social distancing measures (social distance may contribute to reduce infection but not air pollution) are likely to have reduced air pollution.

Air pollution from ozone (O₃), sulfur dioxide (SO₂), nitrogen dioxide (NO₂), and particulate matter (PM) may induce or aggravate asthma.(6) According to a number of published meta-analysis.(7,8) these atmospheric pollutants are associated with higher incidence, prevalence, or worsening of symptoms of asthma and increase hospitalizations. Regarding the short-term effects of air pollutants in terms of exacerbations or worsening of symptoms, three studies have found an association with PM, NO₂, SO₂, carbon monoxide (CO) and O₃.(9) The main pollutant found in traffic and vehicle emissions is NO₂.

So, enforced social distancing and 'shielding' of patients with chronic respiratory disease may have improved symptoms in patients with asthma. However, emerging data on the risk of COVID-19 to people with asthma are inconsistent. Early reports suggested that asthma is not a risk factor for more severe infection with SARS-CoV-2.[10] The prevalence of asthma in two cohorts of patients with COVID-19 in Wuhan, China, was 0-0.9%. Similar statistics were reported in study populations from other countries.[10] Omalizumab (an anti-IgE antibody used in the treatment of severe asthma) may protect against the development of worse COVID-19. Omalizumab enhances anti-viral immunity via a down regulation of the high-affinity IgE receptor on plasmacytoid dendritic cells.[11, 12]

Thus, asthma and treatment with biologic agents (e.g. omalizumab) may prevent infection with SARS-CoV-2 and reduce the severity of COVID-19. Indeed, many countries reported that hospitalizations due to asthma actually dropped substantially during the pandemic.[13] it's not clear whether the decrease was due to a reduction in symptoms or reluctance to visit hospitals. Lockdown with social distancing was the major measure to mitigate cross infection and spread of COVID-19.[14, 15] this sound as we propose omalizumab is the cause of less exacerbation. what about decrease in pollution as a contributing factor for decrease asthma exacerbation as reflected in our title –Agree.

The aim of this study was therefore to determine the impact of the COVID-19 pandemic lockdown and enforced social distancing measures on patients with severe asthma treated with biologic agents.

Methods

Study design

This is a cross-sectional survey study of patients with severe asthma receiving biologic therapy at King Abdulaziz Medical City (KAMC), Riyadh, Saudi Arabia. This is a 1600-bed tertiary-care university hospital. The division of pulmonology has subspecialty clinics including severe asthma clinics. We looked at the effects of the COVID19 lockdown on this cohort of asthmatics on biologic therapy from March till June 2020 over a period of 12 weeks in Riyadh, Saudi Arabia.

Data on levels of air pollution in Riyadh over this period were provided by the Saudi Meteorological office. The lockdown and social distancing rules led to significant reduction in air pollution due to reduced traffic and industrial activities in and around Riyadh.

The study cohort includes all severe asthmatics who are on biologics in KAMC-Riyadh.

The frequency of treatment administration is as per the standard manufacturer's recommendation and FDA approval dosage for various biologic agents. Treatment is administered on site at KAMC by specialist nurses.

We investigated changes in patients symptoms and asthma control (ACT is not about life quality) using the asthma control test (ACT) score after the lockdown and other parameters including, emergency department (ED) visits, hospitalizations, use of oral prednisolone, changes in inhaler therapy, deaths and patient perception of their symptoms in lockdown period.

Table 1
Demographic and other clinical characteristics

		N%
Age (years)	22–30	6(10.7)
	31–40	15(26.8%)
	41–50	11(19.6%)
	51–60	14(25.0%)
	61+	10(17.9%)
Gender	Male	17(30.4%)
	Female	39(69.6%)
Highest level of education	No formal education	9(17.3%)
	Elementary	4(7.7%)
	Primary	6(11.5%)
	High school	11(21.2%)
	University	22(42.3%)
Nationality	Saudi	53(96.4%)
	Non-Saudi	2(3.6%)
Employment status	Employed	21(41.2%)
	Unemployed	5(9.8%)
	House wife	25(49.0%)
Marital status	Single	5(9.6%)
	Married	47(90.4%)
	Divorced	1(1.8%)
City of residence	Riyadh	46(82.1%)
	Outside Riyadh	10 (17.9%)
Biologics used for severe asthma	Omalizumab	47 (84%)
	Mepolizumab	7(12.6%
	Dupilumab	2(3.6%)
Asthma symptoms after curfew and lockdown:	Better	28(50%)

		N%
	Unchanged	22(40%)
	worse	6(10%)
Duration of asthma since diagnosis	4–30 years	
Duration of biologics therapy	5 -120 months	

Table 2
Asthma medication use before and after Covid

Use of bronchodilator and steroid		Before COVID lockdown		After COVID lockdown		P-value
		N	%	N	%	
Daily use ICS	Yes	56	100.0%	55	98.2%	1
	No	0	0.0%	1	1.8%	
Frequency of ICS inhaled steroid use	Twice daily	46	83.6%	41	73.2%	0.034
	Once daily	6	10.9%	9	16.1%	
	As needed for symptoms	3	5.5%	4	7.1%	
	Not using	0	0.0%	2	3.6%	
use Bronchodilator?	Yes	51	92.7%	47	92.2%	1
	No	4	7.3%	4	7.8%	
Delivery of bronchodilator	Inhaler	41	78.8%	42	82.4%	0.67
	Nebulizer	4	7.7%	2	3.9%	
	Both	7	13.5%	7	13.7%	
Frequency of inhaled bronchodilator use	PRN	1	3.2%	1	3.2%	0.502
	daily	5	16.1%	9	29.0%	
	twice daily	0	0.0%	2	6.5%	
	three times or more day	8	25.8%	2	6.5%	
	Once per month	0	0.0%	1	3.2%	
Indication for use of Bronchodilator?	Maintenance therapy for asthma	1	2.0%	4	9.3%	0.343
	Rescue therapy daily	23	46.0%	18	41.9%	
	Rescue therapy up to once per week	13	26.0%	11	25.6%	
	Rescue therapy more than twice per week	13	26.0%	10	23.3%	

ICS: Inhaled corticosteroid

Table 3
asthma control before and after lockdown

ACT score strata	Asthma control score based on ACT				p
	Before COVID-19 pandemic		During lockdown period		
	N	%	N	%	
Uncontrolled ≤ 15	17	30.4%	9	16.1%	0.001
Partially Controlled 16–19	16	28.6%	13	23.2%	
Controlled ≥ 20	23	41.1%	34	60.7%	

Table 4
asthma control score before and after covid

Time point	Asthma control test score		p
	Mean	SD	
Before COVID-19 pandemic	17.3	4.7	< 0.001
During COVID-19 lockdown	19.7	4.5	
Difference	2.4	3.7	

Ethical approval

The institutional review board of KAMC at the King Abdullah International Medical Research Center, Riyadh, Saudi Arabia approved this study.

Sample size estimation

Based on the total number of severe asthma patients registered with the clinic (60), assuming response distribution of 50%, the estimated sample size required to obtain 5% margin of error at 95% level of confidence, was 53. To allow for refusal to participate, all patients registered to attend the severe asthma clinic at KAMC were invited. Only those who consented to the survey were included.

Survey development

The data collection sheet for the telephone survey was reviewed by three consultants who defined and agreed the information required for the survey. The survey had 6 sections.

The first section collected standard demographic data. The second section was about asthma history and the use of biologic therapy. The third section asked about patients' usual maintenance therapy for asthma before the pandemic, and whilst social distancing was enforced during the COVID-19 pandemic. The fourth section was about the effect of COVID-19 pandemic and social distancing on the management of asthma. The fifth section was about need for emergency treatment for asthma during the COVID-19 pandemic and the period of enforced social distancing. This included bronchodilator use,

use of oral steroid for rescue, pharmacy visits, emergency department visits, hospital admission and the last section about asthma control score. The ACT, a validated tool for assessing control of asthma,[16] was incorporated into the sixth section of the survey.

Participants

All patients with severe asthma receiving biologic therapy under follow up in the severe asthma clinic (N=60) were invited to participate in this study. After verbal informed consent, patients who agreed to participate were interviewed by experienced clinicians via telephone.

Study outcomes

The subjective impact of the COVID-19 pandemic and lockdown on the control of asthma in this cohort was inferred from participants' reported perception of control of asthma and changes in maintenance medication use. The ACT score was used as an objective assessment of control of asthma. When using the ACT score to evaluate interventions it has been recommended that a change of 3-points is a minimally important difference (MID i.e. smallest clinically significant change).[16] The difference in ACT scores was therefore calculated, and the factors associated with changes greater than the MID were assessed.

Patients were also stratified into three groups based on the ACT (uncontrolled (UC) < 16, partially controlled (PC) 16-19, and controlled (C) 20-25) as per The Global Initiative for Asthma (GINA) Guidelines 2019.[17] The objective impact was determined by absolute differences in the ACT scores and changes in numbers of patients in these strata. To screen for response bias, patients reported time since diagnosis of asthma, duration of biologic therapy, prescription medications, ED visits and hospital admissions were cross-checked against electronic medical records.

Statistical analysis

Data were entered and analyzed using IBM SPSS Statistics for Windows Version 24. IBM Corp. Categorical data are presented as frequencies and percentages and the marginal homogeneity test or McNemar's Chi squared test was used to compare the marginal proportions distributions of all categorical data. Numerical data are presented as means \pm SD and compared using Student's t-test for paired data. A test with a p-value < 0.05 was considered to be statistically significant.

Results

Demographics

Participants' demographic data are shown in Table 1. A total of 56, Female 39;(69%0; mean age \pm SD 47.4 \pm 13.8 years The majority of participants were Saudi (53; 95%), married (47; 84%), resident in Riyadh (46; 82%), Most patients had been treated with Omalizumab (47; 84%); the rest received Mepolizumab (7; 12.5%) and Dupilumab (2; 3.6%). All these patients had been on biologic therapy for > 5 months.

Asthma duration, biologics add-on therapy and use of inhaled bronchodilator, inhaled corticosteroid biological therapy before COVID-19 pandemic

In this cohort, the mean time since diagnosis of asthma was 19.6 years (SD 11.5 years). The majority of these patients (54; 95%) regularly attended the outpatient clinics for severe asthma under specialist care. Most of the patients agreed that their symptoms of asthma had improved with biologic therapy (45; 80.4%). Their reported use of inhaled bronchodilator and inhaled corticosteroid before the COVID-19 pandemic is detailed in Table 2.

When asked, 28 subjects (50%) in this survey reported that their asthma symptoms were better overall during the COVID-19 lockdown period. This statement is supported by the reported reduction in bronchodilator inhaler therapy in 23 (41%) and inhaled steroids in 15 (26.8%) of patients

The subjective effects of the COVID-19 pandemic and social distancing on the overall control of participants' asthma is detailed in Table 3.

Asthma control test scores before and after 12 weeks of the COVID-19 lockdown period

As shown in Table 3 participants' mean ACT scores before ($17.3 \pm \text{SD } 4.7$) and after 12 weeks of the COVID-19 lockdown ($19.7 \pm \text{SD } 4.5$) suggested significant improvement in control of asthma (mean difference $2.4 \pm \text{SD } 3.7$; $p < 0.001$). Of the 38 (67.9%) participants whose ACT scores increased, 18 (32.1%) achieved the MID (≥ 3 points). Furthermore five of these 38 participants had a remarkable improvement in their ACT scores (≥ 9 points). However, 16 participants' scores (28.6%) did not change, and 2 (3.6%) fell.

Participants' ACT scores stratified into uncontrolled, partially controlled, and controlled groups are detailed in Table 4. Importantly, 13 participants improved, and joined the controlled group from either the uncontrolled (5, 8.9%) or partially controlled (8, 14.3%) groups. Three participants (5.4%) improved and joined the partially controlled group from the uncontrolled group. However, two participants deteriorated and moved from the controlled group to the partially controlled group. Of these, one, whose ACT score dropped 5 points, had received biologic therapy but, because of side effects (urinary retention and constipation), had stopped other all medications. As a result, she had also needed to visit the ED.

The marginal homogeneity test demonstrated a statistically significant difference between the marginal proportions' distributions of these groups ($p = 0.001$) before, and after 12 weeks of the lockdown period. Furthermore, the most interesting observation in the study was an increase in the proportion of patients who were controlled before and after 12 weeks of the lockdown [23 (41%) Vs 34 (60.7%)] When all participants whose ACT scores increased were compared with those whose did not, no statistically significant differences in age, gender, employment status, highest level of education achieved, marital status, difficulty obtaining medications, pharmacy treatment, oral steroid use, ED visits, or failure to receive scheduled biologic therapy were found.

Quality of air and pollution during COVID-19 Lockdown period in Riyadh Region, March-June 2020

Riyadh region was lockdown by authorities to contain the spread of COVID-19 virus by imposing strict curfew in March 2020. All traffic and industrial activity were significantly reduced during this lockdown period. The resulting reduction in vehicular and industrial activity led to significant improvement in quality of air and reduce pollution as is shown in Fig.1. Levels of carbon monoxide (CO), Sulphur dioxide (SO₂) and nitrous oxide (NO₂) were all shown to decrease in Riyadh region compare to the months before the lockdown. All these pollutants are directly linked with the traffic and industrial activity in the area. This improvement in quality of air has favorable effects in people with respiratory diseases in general but asthma in particular. Approximately half of participants (30; 53.6%) believed that the improvement in their asthma was related to reduction in air pollution during the period that social distancing was enforced.

Discussion

The majority of our cohort of patients with severe asthma were actively being treated with biologic agents. Half subjectively reported improvement, and a third had a clinically significant improvement in ACT score (≥ 3 points) during the COVID-19 pandemic and enforced social distancing. Furthermore, as defined by their ACT score groups; nearly 25% improved and moved from either the uncontrolled or the partially controlled groups to the controlled group.

A significant proportion of the reduction in hospitalizations probably reflected improvement in patients' asthma. This improvement occurred as a result of the many psychological, behavioral, environmental, and healthcare-related changes that occurred during the 12 weeks lockdown period. These changes could be considered an 'asthma care bundle'. This package of interventions resulted in statistically and clinically significant improvement in control of asthma as defined movement into the controlled ACT score group from another group (i.e. uncontrolled or poorly controlled).

The scope of this study cannot exclude other factors that may have been relevant to the improvement of asthma in this cohort. However environmental control is most obvious factor that changed over the 12 weeks period of this study. Atmospheric pollution is a well-recognized precipitant of asthma attacks.[6, 14] Reductions in this will probably be relevant.[18] Indeed, the meteorological and environmental report for Riyadh stated that atmospheric pollution fell during the COVID-19 lockdown period due to reduced traffic and industrial activities [19]. While more than 50% of the patients in this study reported an improvement in their asthma symptoms during the lockdown period, more than half attribute this to a reduction in road traffic activities.

March is a spring season in Riyadh and so viral infections and common outdoor allergens such as dust, pollen and fungal spores are less prevalent in this season. However reduced exposure to these precipitants as a result of social distancing measures could also be factors in improvement of symptoms.

The improvement in this cohort could also reflect increased compliance with asthma treatments for fear of getting COVID-19. However, some patients reduced their inhalers whilst others self-medicated with rescue oral steroids or took over-the-counter medications. The patients in this cohort have significant

experience in the self-management of asthma (mean time from diagnosis was over 19 years). So those who self-medicated during the lockdown will probably have used this strategy to avoid hospitalization prior to the pandemic. Regardless, some of the fall in hospitalizations probably reflected self-management of mild exacerbations of asthma. Other reasons could include reduced exposure to allergens and prevention of transmission of all respiratory viruses during lockdowns.[13]

A single case report describes the course of symptomatic COVID-19 in a 52-year-old man treated with omalizumab for severe allergic asthma.[11] Remarkably, this patient did not develop pneumonia or an exacerbation of asthma. Patients with allergic asthma may have a lower risk of developing severe COVID-19, and omalizumab can enhance immunity against viruses.

Further research to identify the factors which contributed to the reduction in hospitalizations of patients with asthma during the COVID-19 pandemic and social distancing is required.

Strengths And Limitations

There is a lack of knowledge about bronchial asthma control during Covid-19 pandemic. Major strength of this study is the addition of our knowledge about asthma during the current pandemic. Secondly it included patients with severe asthma where the effects of environmental changes or social distances measures may will be obvious compared to other less severe asthma. Reported data obtained at interview can be associated with response bias and so its accuracy can be questioned. However, participants' accounts of ED visits, hospital admissions, prescribed medications, and attendance for administration of biologic therapy were consistent with hospital electronic medical records. Studying a clearly defined cohort of patients with severe asthma, attending a specialist clinic, at a single tertiary care center, where biologic agents are regularly prescribed, provided good internal validity. Consequently, external validity and generalizability may be restricted. However, our survey had a high response rate and our institution serves one of the largest caseloads of patients with severe asthma in Saudi Arabia. Our respondents are therefore likely to be representative of patients with severe asthma treated with biologic agents worldwide.

Conclusions

Many of our patients reported improvement in their asthma during the 12 week COVID-19 lockdown period. This subjective improvement is also consistent with objective assessment of control of asthma using the ACT score as well as ER visits, Hospital admissions, prescription medications and attendance for their biologic treatment administration. Many of the patients in this survey attribute this improvement to reduction in atmospheric pollution due to reduced road traffic activity during the lockdown period. The data on air pollution in Riyadh during this period would tend to support this.

Declarations

Ethics approval and consent to participate: This retrospective, observational study was approved by the institutional review board (IRB) of the King Abdullah International Medical Research Center, Riyadh, Saudi Arabia.

Availability of data and material

All authors affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained. The data that support the findings of this study are available from King Abdulaziz Medical City (KAMC), Ministry of National Guard – Health Affairs, Riyadh, Saudi Arabia. However, restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with permission of KAMC.

Competing interests

All authors declare that there are no conflicts of interest with respect to this study.

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Figures



Fig.1 Environmental Data (CO, SO2, NO2 related to vehicular and industrial activity) for Riyadh Region March-June 2020
 Source: Saudi Arabia General Authority for Meteorology and Environmental Protection

Figure 1

Figure 1