

Original Research Article

Study of The Fasting of Ramadan on Asthmatic Patients and The Outcome with Treatment Modification

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Abstract

Ramadan, the 9th month of Islamic calendar ranging for 29-30 days in duration, during which Muslims are fasting . It was demonstrated that most of the asthmatics Muslim in our regions did not consider asthma to be a problem to Ramadan, and they pass in fasting by arranging their treatment as use the controller inhaler on Iftar and Sohoor time & stop taking the reliever inhaler in the day time. the Aim is to study the effect of Ramadan fasting on the clinical, spirometric figures of patients with stable asthma with treatment modification . Methods: A prospective cohort study was performed before, during and after Ramadan fasting on well-controlled asthmatic patients as they were classified according to the treatment types as:
group 1: on inhaled budesonide + formoterol fixed single device (symbicort, Astra Zeneca, sewed) + on need short acting B adrenergic agonist.
group 2 : short acting B adrenergic agonist on needed alone
group 3: interleukins antagonists tablets Once daily (10 mg montelukast Na tablet) + short acting B adrenergic agonist on needed. Results found that fasting seen to have detrimental effects on fasting in hot weather as FEV1, FEF in 50% and asthma control test score show statistically significant differences before & after fasting but patient on inhaled symbicort with treatment modification show better outcome.

Key Words: Asthma control, asthma treatment modification, Ramadan fasting, symbicort inhaler.

الخلاصة

شهر رمضان هو الشهر التاسع من التقويم الإسلامي يتراوح طوله من ٢٩-٣٠ يوما في مدة خلالها المسلمون يصومون . وقد تبين أن معظم المسلمين المصابين بالربو في مناطقنا لا يعتبر الربو مشكلة لصيام شهر رمضان انهم يقومون بالصيام مع تحويل العلاج لياخذ في اوقات الفط و السحور فقط و التوقف عن الاستخدام في النهار والهدف من البحث هو دراسة تأثير صيام شهر رمضان المبارك على المرضى سريريا و أرقام وظائف الرئة للمرضى الذين يعانون من الربو مستقرة مع تعديل العلاج . الطرق: تم إجراء دراسة قبل وأثناء وبعد شهر من صيام رمضان لمرضى الربو المسيطر عليه بشكل جيد، كما تم تصنيفها وفقا لأنواع العلاج على النحو التالي :

- مجموعة ١: الجهاز المخلوط الثابت الجرعة من (بوديسونيد + فورموتيرول) (symbicort، استرا زينيك، خيط) +البخاخ القصيرة التمثيل B الأدرينالية عند الحاجة.

- المجموعة ٢: البخاخ القصير التمثيل B الأدرينالية عند الحاجة وحدها.

- مجموعة ٣: دواء مغير مادة الانترلوكين مرة واحدة يوميا (١٠ ملغ مونتيلوكاست نا قرص) +بخاخ القصيرة التمثيل B الأدرينالية عند الحاجة بصورة عامه الصيام في الاجواء الحارة قد يؤدي الى تأثيرات سلبية لدى مرضى الربو مع نتائج افضل لدى المرضى المستخدمين لعلاج الجهاز المخلوط الثابت الجرعة من (بوديسونيد + فورموتيرول) (symbicort، استرا زينيك، خيط) +البخاخ القصيرة التمثيل B الأدرينالية عند الحاجة.

الكلمات المفتاحية: السيطرة على الربو، تغيير علاج الربو، صيام رمضان، عقار السمباكورت.

Introduction

Ramadan, the 9th month of the Islamic calendar, during which Muslims are stop having foods, water and drinks, sexual relationships, and having cigarette from the start of the fasting at sunrise till the end at sunset for a duration varies with the seasons of the year and the site of the country [1].

All healthy persons Muslims are advised to fast, with few exception as children, weak elderly, during a trips [2], ladies during their menstrual cycle time, late in pregnancy, and breast feeding [2,3].

Although many studies were carried out on the effects of the fasting state on chronic medical diseases as rheumatoid arthritis [4,5], diabetes [6], hypertension and congestive heart failure [7] in asthma were very limited [8-10]. In addition the majority of the papers concentrate on pulmonary function test parameters changes during fasting in healthy subjects [11-14].

Ramadan fasting & medications:

Asthma patients are generally managed by: regularly use drugs to overcome the symptoms, patient explanation with education, patient follow up, and correction and omitting the risk factors [15, 16].

But unfortunately, it was seen that a big number of patients do not compliance fully with their management aims. Medications-related parameters as difficult-use inhalers, unwanted effects, and cost of the medications, are the major causes for non or partial adherence to the inhale drugs [17].

poor adherence to the inhaled drugs can in addition be augmented by some social personal issues as the beliefs and desires [18].

It is clear that the majority of the asthmatic patients are not concern that asthma is a problem during the state of fasting, and they enter in the Ramadan fasting by modifying the treatment as use the

controller inhaler in non-fasting time (the night) and omit the use of the rescue drug in the fasting time (the day) [19].

The aims of the study are to see the Ramadan fasting state affection on the clinical, spirometric figures of patients with stable asthma, to state these effects due to fasting itself or due to treatment modification, to observe any correlation between these changes and the baseline treatment types, and finally to assess the safety of the treatment modification in the fasting time.

Materials and Methods

Study Design:

A cohort study is done on asthmatic patients group, The study was conducted in outpatient private clinic in Babylon province in Iraq in the Ramadan 1437 Hijri year (June-July, 2016).

The mean duration of fasting per a day is 16 hours in a hot weather as the temperature shoot to around 50 C.

Subjects were asked and examined for the following:

- The treatment used for his asthma in the last 3 months
- Asthma control test (ACT) score and spirometric assessment are calculated at baseline one month before fasting while they are on their stable treatment then immediately when the Ramadan fasting month is settled (1 month) with the treatment modification then after another 1 month of non-fasting state with the same modification of the treatment done in the fasting state.
- count the number of fasted days and the reason for non-fasting
- drugs regiment modification as:
 - A- patient on inhaled budesonide + formoterol fixed single device (symbicort) + on need short acting B adrenergic agonist: change time of ICS use from 12 hourly as usual to used once daily at night or not using short acting B adrenergic agonist (SABA) inhaler as needed in the fasting hours during the day
 - B- patients on SABA only: avoid taking SABA in the day time

C- patient on interleukins modifiers (ILM) +SABA: continue to take oral tables on night only & avoiding taking SABA on day time.

- need for hospitalization for asthma related causes during the fasting month.
- reporting any local side effects of symbicort namely dysphonia (change in the voice noticed by the patient or his relative) or oro-pharyngeal fungal infection (detected by the patients or by the clinical exam.)

Patients

52 stable asthmatic patients that their clinical features and drugs therapy were fixed during the last 3 months were included in the study. Their disease state were defined depending upon the criteria of Global Initiative on Asthma (GINA) [18].

The enrolled Patients data were recorded as age, weight, height, and the body mass index (BMI) were measured .

The patients is classified according to the treatment types as:

- group 1: on symbicort + on need SABA
- group 2 : SABA on needed alone
- group 3: interleukins antagonists tab. Once daily (10 mg montelukast Na tablet) + SABA on needed

Exclusion criteria:

- 1- patients refused participation in the study or with mental or psychological state that prevent understanding or doing the study.
- 2- Patients who had sustained an attack of exacerbation in the last three months
- 3- Patients classified as unstable by ACT score ≤ 19 points at the first pre-fasting evaluation.

4- Any patients with pharmacotherapy instability in the last 3 months

5- concomitant disease that prevent fasting as insulin dependent diabetes mellitus or acute myocardial infarction.

6- Child –bearing and nursing ladies.

7- those with a days of fasting less than 20 days for reason other than asthma problems.

8- Any patients with already dysphonia or oro-pharyngeal fungal infection due to any cause.

The intensity of symptoms are measured by a validated Asthma Control Test (ACT) questionnaire. [18]

Spirometry:

A Spirometry was done in the include patients . the test was done 3 times (one week before the fasting month, one week after the Ramadan fasting cessation and after one month from the last test) using an electronic device (Spirolab III, MIR, Italy) while the patients are set on a chair with the nose closed by a specific clip. The measurements of 2 lung function parameters :(FEV1) & (FEF50) was done every time the Spirometry conducted to the patients as indicators for airway diseases .

Results

Distribution of Patients According to Socio-demographic Characteristics

As shown in Table1 the Mean age & BMI are (38.36 ± 10.14) and (28.66 ± 3.82) respectively with the majority of patients (61.5%) were men.

The mean days of fasting is 26.75 ± 2.01 from 22-29 days mostly due to non-asthma related causes mostly travelling or in female their menstruation (both are legal excuse for non-fasting).

Table 1: Distribution of asthmatic patients according to socio-demographic characteristics

Socio-demographic variables		
Age (years)	(38.36 ± 10.14)	(18-65)
BMI (Kg/m^2)	(28.66 ± 3.82)	(22-37)
Gender		
Male	32	61.5%
Female	20	38.5%
Total	52	100.0%

Distribution of Patients According to Type of Treatment

Figure 1 shows the distribution of the patients according to type of treatment, as shown the three groups are matched.

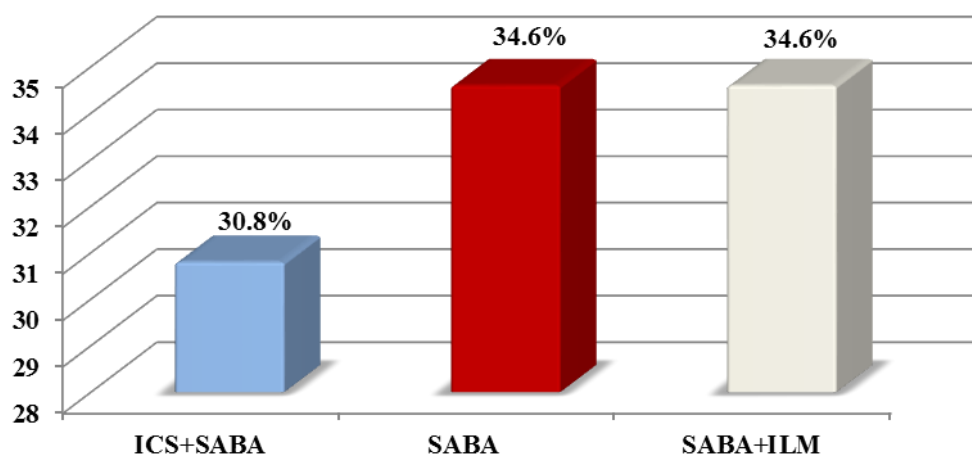


Figure 1: Distribution of asthmatic patients according to type of treatment

Distribution of Patients According to post-treatment modification side effects

There was no statistically significant differences with any treatment

modification regarding appearance of new effects as shown on table 2.

Table 2: Distribution of patients according to post-treatment modification side effect.

Treatment modification side effect		
Fungal infection after treatment modification		
Yes	0	0.0%
No	52	100.0%
Total	52	100.0%
Dysphonia after treatment modification		
Yes	3	5.8%
No	49	94.2%
Total	52	100.0%

+Fasting duration was 16 hours for all patients.

Mean Differences of FEF 50%, FEV1, ACT-Score before & after Fasting Days

Table 3 shows mean differences of FEF50%, FEV1 and ACT-Score before and after fasting days. There were significant differences between means of

FEF50%, FEV1 and ACT score before and after fasting days meaning that those patient have some affection by fasting in hot weather and for a long hours as expected.

Table 3: Mean differences of FEF, FEV1 and ACT-Score before and after fasting days with treatment modification

Variable	Categories	N	Mean	Paired t-test	P value
FEV1	Before fasting	52	50.26 ± 8.42	6.509	<0.001*
	After fasting	52	45.84 ± 10.69		
FEF50%	Before treatment	52	48.65 ± 11.3	6.056	<0.001*
	After treatment	52	44.25 ± 13.45		
ACT-score	Before treatment	52	22.59 ± 1.69	15.96	<0.001*
	After treatment	52	18.61 ± 2.41		

+Modification of treatment done for all patients, *p value ≤ 0.05 was significant

Mean Differences of FEF50%, FEV1 and ACT-Score before Fasting and after one Month of Non Fasting Days with same treatment modification

Table 4 shows mean differences of FEF50%, FEV1 and ACT-Score before fasting and after one month of non-fasting days with same treatment modification.

There were significant differences between means of FEF50%, FEV1 and ACT score before fasting and after one month of non-fasting days indicating that the effect of the fasting on asthma control may be due to treatment modification not due to the fasting itself.

Table 4: Mean differences of FEF, FEV1 and ACT-Score before fasting and after one month of non-fasting days

Variable	Categories	N	Mean	Paired t-test	P value
FEV1	Before fasting	52	50.26 ± 8.42	3.913	<0.001*
	After one month of non-fasting days	52	48.61 ± 8.25		
FEF	Before treatment	52	48.65 ± 11.3	3.182	0.002*
	After one month of non-fasting days	52	47.57 ± 11.01		
Cat-score	Before treatment	52	22.59 ± 1.69	8.852	<0.001*
	After one month of non-fasting days	52	20.98 ± 1.32		

+Modification of treatment done for all patients, *p value ≤ 0.05 was significant

Mean Differences of FEF50%, FEV1 and ACT-Score before and after Fasting Days for Group 1

Table 5 shows mean differences of FEF50%, FEV1 and ACT-Score before and after fasting days for group 1 (on symbicort +SABA). There were significant differences between means of ACT score before and after fasting days, while there were no significant differences between means of FEF50% and FEV1 before and after fasting days meaning that by using

single daily dose of symbicort during fasting state does not disturb the spirometric parameters although the ACT score show a significant statistical difference and this differences are maintained after one month on same treatment modification with non-fasting state as shown in table 6 mean that the single daily dose of symbacort treatment can maintain the spirometric parameters in spite of ACT difference which is a little bit subjective.

Table 5: Mean differences of FEF, FEV1 and ACT-Score before and after fasting days for Group1

Variable	Categories	N	Mean	Paired t-test	Z	P value
FEV1	Before fasting	16	52.00 ± 8.17		-0.13	0.896
	After fasting	16	51.56 ± 10.98			
FEF	Before treatment	16	53.00 ± 11.08	0.526		0.606
	After treatment	16	52.56 ± 11.80			
ACT-score	Before treatment	16	22.93 ± 1.65		-3.57	<0.001*
	After treatment	16	20.37 ± 2.62			

+Modification of treatment done for all patients,*p value ≤ 0.05 was significant

Table 6: Mean differences of FEF, FEV1 and ACT-Score before fasting and after one month of non-fasting days for Group1

Variable	Categories	N	Mean	Paired t-test	Z	P value
FEV1	Before fasting	16	52.00 ± 8.17		-0.736	0.462
	After one month of non-fasting days	16	51.43 ± 9.32			
FEF	Before treatment	16	53.00 ± 11.08		-0.265	0.791
	After one month of non-fasting days	16	52.87 ± 10.94			
ACT-score	Before treatment	16	22.93 ± 1.65	6.708		<0.001*
	After one month of non-fasting days	16	20.68 ± 1.53			

+Modification of treatment done for all patients,*p value ≤ 0.05 was significant

Mean Differences of FEF50%, FEV1 and ACT-Score before and after Fasting Days for Group 2

Table 7 shows mean differences of FEF50%, FEV1 and Cat-Score before and after fasting days for group 2 (on SABA). There were significant differences between means of FEF50%, FEV1 and ACT score

before and after fasting days meaning the control is completely lost with the spirometric and ACT parameters with fasting and this modification and the effect continue even one month of non-fasting but on same modification as shown in table 8.

Table 7: Mean differences of FEF, FEV1 and Cat-Score before and after fasting days for Group2

Variable	Categories	N	Mean	Paired t-test	P value
FEV1	Before fasting	18	49.72 ± 9.4	7.2	<0.001*
	After fasting	18	42.33 ± 8.55		
FEF	Before treatment	18	47.72 ± 9.76	5.471	<0.001*
	After treatment	18	40.66 ± 10.00		
ACT-score	Before treatment	18	22.83 ± 1.61	15.417	<0.001*
	After treatment	18	17.61 ± 1.5		

+Modification of treatment done for all patients,*p value ≤ 0.05 was significant

Table 8: Mean differences of FEF, FEV1 and Cat-Score before fasting and after one month of non-fasting days for Group2

Variable	Categories	N	Mean	Paired t-test	P value
FEV1	Before fasting	18	49.72 ± 9.4	6.768	<0.001*
	After one month of non-fasting days	18	47.44 ± 7.84		
FEF	Before treatment	18	47.72 ± 9.76	-3.09	0.002*
	After one month of non-fasting days	18	45.88 ± 8.80		
Cat-score	Before treatment	18	22.83 ± 1.61	2.483	0.024*
	After one month of non-fasting days	18	21.05 ± 1.01		

+Modification of treatment done for all patients, *p value ≤ 0.05 was significant

Mean Differences of FEF50%, FEV1 and Cat-Score before and after Fasting Days for Group 3

Table 9 shows mean differences of FEF50%, FEV1 and ACT-Score before and after fasting days for group 3 (on ICS+ILM). There were significant differences between means of FEF50%,

FEV1 and ACT score before and after fasting days again meaning that this modification fail to protect the patients during the fasting state and this is also remain after one month of non-fasting state with the same treatment modification as shown in table 10.

Table 9: Mean differences of FEF, FEV1 and ACT-Score before and after fasting days for Group3

Variable	Categories	N	Mean	Paired t-test	P value
FEV1	Before fasting	18	49.27 ± 7.82	5.265	<0.001*
	After fasting	18	44.27 ± 10.80		
FEF	Before treatment	18	45.72 ± 12.37	5.04	<0.001*
	After treatment	18	40.44 ± 15.04		
ACT-score	Before treatment	18	22.05 ± 1.76	11.351	<0.001*
	After treatment	18	18.05 ± 2.2		

+Modification of treatment done for all patients, *p value ≤ 0.05 was significant

Table 10: Mean differences of FEF, FEV1 and ACT-Score before fasting and after one month of non-fasting days for Group3

Variable	Categories	N	Mean	Paired t-test	P value
FEV1	Before fasting	18	49.27 ± 7.82	3.367	0.004*
	After one month of non-fasting days	18	47.27 ± 7.44		
FEF	Before treatment	18	45.72 ± 12.37	2.016	0.05*
	After one month of non-fasting days	18	44.55 ± 11.9		
ACT-score	Before treatment	18	22.05 ± 1.76	3.189	0.005*
	After one month of non-fasting days	18	21.166 ± 1.33		

+Modification of treatment done for all patients, *p value ≤ 0.05 was significant

Discussion

The mean age of the patient is seen in young as expected to find asthma in young active working age group with most of them male as the male seek medical advice earlier in our society with most of them overweight which may be due to the association between the asthma and obesity in adult or the effect of the disease make them inactive with poor exercise tolerance and performance or due to the use of treatment that affect the weight as systemic steroid, all the above findings are consistent with the facts of asthma epidemiology.

There were no appearance of new side effects with all types of treatment modifications as the modifications is not so serious and radical and for a short time & that sound logical as reduction the dose & the frequency of the inhaled steroid can reduced the local side effects.

Regarding the effect of the fasting on the asthma parameters: Generally it shown that those patients show clinical and spirometric affections with fasting and treatment modifications and these effects remain after keeping the same treatment modifications with non-fasting state for another one month after Ramadan fasting indicating that this detrimental effects of fasting on asthma control may be due to treatment changes not the fasting itself, these finding are expected as in any chronic diseases any treatment modification toward reduction expected to be detrimental but unfortunately there are no similar studies for comparing.

Regarding the effects with each group of treatment modification: The patients on single symbicort treatment show better outcome as the spirometric parameters remain controlled with this modification during & after fasting, this finding is logic as the duration of action of the symbicort components are long & extend to cover the whole day while the other treatments modification cannot achieve this gain as the duration of action is not durable

enough, again there are not similar studies for comparing.

Conclusion

Fasting in hot weather may have some detrimental effect on asthma control may be due to treatment modifications. Patients on symbicort treatment showed better tolerance to fasting even with modification as a single night dose. Patients on other regiments show worse outcome with fasting and treatment modification. All the treatment modification show no side effects so the modification is safe on short term effect.

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