

The effect of Ramadan fasting on quiescent systemic lupus erythematosus (SLE) patients' disease activity, health quality of life and lipid profile: a pilot study

Hamid Goharifar^{1,2} · Seyedeh Tahereh Faezi¹ · Pedram Paragomi¹ · Ali Montazeri³ · Arash Tehrani Banihashemi¹ · Maryam Akhlaghkah¹ · Bahar Sadeghi Abdollahi¹ · Zahra Kamazani¹ · Mahmood Akbarian¹

Received: 26 February 2015 / Accepted: 5 May 2015 / Published online: 14 May 2015
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Abstract SLE is a common autoimmune disease with considerable morbidity. Ramadan fasting is a religious custom Muslims regularly practice. We aimed to evaluate the effect of Ramadan fasting on SLE patients' disease activity, health quality of life and lipid profile. We conducted this case control study as a pilot study in 40 quiescent SLE patients, 21 cases who decided to fast and 19 controls who decided not to have Ramadan fasting between August and November 2009 in lupus unit of Rheumatology Research Center in Tehran University of Medical Sciences, Iran. They were assessed for SLE Disease Activity Index, lipid profile and quality of life with

Short-Form 36 (SF-36) Health Survey, 1 day before Ramadan, the day after and 3 months after Ramadan fasting. After 24.1 ± 5.4 (mean \pm SD) days of fasting, anti-ds DNA increased for 0.34 ± 0.41 mmol/dL in cases versus 0.07 ± 0.31 in controls ($P = 0.026$). Likewise C3 increased more dramatically in cases (16.8 ± 17.5 vs. 2.3 ± 13.2 mg/dL, $P = 0.006$). Three months after fasting, anti-ds DNA was still increased 0.28 ± 0.46 mmol/dL in cases while a 0.02 ± 0.43 mmol/dL drop in controls was detected ($P = 0.04$). On the contrary, C3 returned to baseline. These changes were not accompanied with significant changes in disease activity and health quality of life. Ramadan fasting had no effect on lipid profile except for delayed total cholesterol decrease in cases in comparison with controls (16.4 ± 29.4 decrease vs. 4.6 ± 23.9 mg/dL decrease, $P = 0.018$). Ramadan fasting probably has no detrimental effect on SLE patients' disease activity and their quality of life in the quiescent phase of disease.

Keywords Systemic lupus erythematosus · Disease activity · Lipid profile · SF-36

Introduction

SLE is the second most prevalent multisystemic autoimmune disease after rheumatoid arthritis (RA) which affects mainly young women in reproductive age. SLE is associated with considerable morbidity and mortality especially due to atherosclerosis, infection and renal involvement.

Ramadan fasting is a model of moderate dietary restriction in which healthy non-traveler Muslims are religiously forbidden to eat, drink or smoke for 29–30 consecutive days a year from dawn to dusk. Ramadan is the ninth month of Lunar Hegira year which is 11 days shorter than

✉ Pedram Paragomi
Pedram.paragomi@gmail.com

Hamid Goharifar
h.goharifar@yahoo.com

Seyedeh Tahereh Faezi
s.t.faezi@yahoo.com

Arash Tehrani Banihashemi
tehranib@gmail.com

Maryam Akhlaghkah
Maryam.akhlaghkah@gmail.com; ali@jdcord.jd.ac.ir

Bahar Sadeghi Abdollahi
baharsadeghi@gmail.com

Zahra Kamazani
Zahra.kamazani@hotmail.com

Mahmood Akbarian
akbarian@neda.net

¹ Rheumatology Research Center, Tehran University of Medical Sciences, Tehran, Iran

² Department of Internal Medicine, Hamedan University of Medical Science, Hamedan, Iran

³ Iranian Institute for Health Sciences Research, Tehran, Iran

solar year, so fasting is variable between 11 and 18 h with respect to its season and place.

Fasting may affect SLE patients by its direct effect on immune system or may act indirectly via neuroendocrine axis. Although severe and prolonged dietary restriction has detrimental effects on immune system [1], moderate restriction may ameliorate autoimmune diseases without facilitating infections [2, 3].

In an experimental model of SLE, 40 % of nutritional restriction delayed the development of renal involvements in a significant fashion. This is especially due to suppression of antigen-activated T cells without considerable effect on their naïve counterparts and no increase in IFN- γ , IL-12, IL-10, TNF- α or NF κ B [4, 5]. The ameliorative effects of Ramadan fasting have been proved in RA and ulcerative colitis [6, 7].

It is not clear whether Ramadan fasting has an early or delayed ameliorating effect on SLE patients similar to moderate dietary restriction in animal models or a detrimental effect due to the stress of nutrient abstinence. This is an important issue for SLE patients to understand the clinical outcome of exercising Ramadan fasting. The objective of this study was to clarify the response of this question along with the early and delayed effect of Ramadan fasting on their disease activity, health quality of life and lipid profile. Two later items have not been fully addressed in SLE patients.

Patients and methods

We conducted this pilot observational study in SLE patients in order to evaluate the effect of Ramadan fasting on disease activity, BMI, lipid profile and health quality of life. This case–control study was between the ninth (Ramadan) to the end of the twelfth (Dhu al-Hijjah) month of 1430 (Lunar Hegira) corresponding to August and November 2009 in lupus unit of RRC in TUMS, Iran. This recruitment began since 2 weeks before till the beginning of Ramadan.

These patients had SLE according to ACR 97 criteria, lived in Tehran and had no evidence of major infection or active disease in recent 6 months. Patients with hemolytic anemia, new or exacerbated thrombocytopenia ($<100,000/\mu\text{L}$), kidney involvement (granular or cellular cast or >500 mg/day proteinuria), convulsion, psychosis, organic brain disorder, vasculitis, thrombotic event, myositis, myocarditis or pulmonary involvement (pneumonitis or diffuse alveolar hemorrhage) were excluded. The enrolled patients did not receive cytotoxic or biologic agent, and their prednisolone consumption was <15 mg/day.

After taking history and performing physical examination by a rheumatologist, the questionnaire of Iranian version of Health Survey Short Form with 36 questions

(SF-36) [8] was completed by patients with guidance of an experienced technician and body mass index (BMI) was measured by her. Then blood samples of patients were assessed for cell blood count, anti-ds DNA, C3, C4, CH50, erythrocyte sedimentation rate (ESR), triglyceride (TG) (normal range <250 mg/dL), cholesterol (normal range <200 mg/dL), low-density lipoprotein (LDL) (normal range ≤ 130 mg/dL) and high-density lipoprotein (HDL) (normal range ≥ 40 mg/dL) and urine for cellular and granular casts and protein for assessment of SLE Disease Activity Index (SLEDAI), physician global assessment (PGA), flare-up intensity (FUI) [9], lipid profile and SF36, 1 day before Ramadan (first visit). We repeated this process the day after Ramadan fasting (second visit) and 3 months thereafter (third visit) in both groups by the same personnel and laboratory equipments. The difference of each variable mean between case and control group was calculated in these three times. We compared this difference between second and first visits and then third and first visits and reported these differences as early and late effects of Ramadan fasting on mentioned variables. WBC and platelet were counted by automatic impedance counter and hemoglobin in cyanmethemoglobin method all by Sysmax-XS-800i. C3 (normal range 55–120 mg/dL) and C4 (normal range 10–50 mg/dL) were detected by turbidometry, anti-ds DNA (normal <20.0 mmol/dL) and CH50 (normal range 30–75 hemolytic unit/mL) by ELISA, ESR by Westergren tubes, lipid profile by enzyme dissociation and spectrophotometric assay, urine sediment by microscopic counting of cells and casts and protein by dipstick.

We did not interfere in the extent of calorie restriction and nutritional profile in case and control groups. The dose of prednisolone was fixed during Ramadan fasting and 3 months thereafter without any adjustment in case or control subgroups. Patients had no pregnancy or lactation, and Ramadan fasting had no interference with drug schedule of patients in this period of time.

Primarily, we enrolled 80 quiescent SLE cases who had decided to participate in our study. These patients were collected from our SLE database which contained 1152 patients. We had 38 patients who had decided to practice Ramadan fasting and 42 patients without this decision. Twenty-one patients enrolled as case subgroup (fasting) and 19 patients assigned to the control subgroup (non-fasting). Sample size was decided to be small ($n = 40$) due to probable risks of fasting in SLE and the absence of similar previous study in the literature.

We analyzed data by SPSS version 22.0 (Chicago, IL). Normality or abnormality in distribution of variables was assessed by nonparametric one-sample Kolmogorov–Smirnov test. Comparisons were made by independent sample T test and nonparametric Mann–Whitney test

for variables with normal and abnormal distributions, respectively.

Patients in both groups signed informed consent, and the study was approved by Ethical Committee of TUMS.

Results

We assigned 40 SLE patients including 21 cases (52.5 %) and 19 (47.5 %) controls, all were female. Mean age of cases was 39.7 ± 13.4 years, while mean age of controls was 40.2 ± 11.2 years ($P = 0.90$). No significant difference in disease duration between cases and controls was present (11 ± 8.1 vs. 11.6 ± 9.4 years; $P = 0.8$).

The SLEDAI ratio between second and first visits did not show significant differences in cases and controls ($P = 0.71$). Likewise SLEDAI ratio between third and first visits was comparable in two subgroups ($P = 0.55$).

All patients in case group had practiced fasting for 14.47 ± 0.58 h a day for 24 ± 6 days. Twenty-four hours after ending of Islamic fasting, anti-ds DNA increased to $0.34 (\pm 0.41)$ mmol/dL in case versus control $0.07 (\pm 0.31)$ group ($P = 0.026$). This difference continued till 3 months after relative to the beginning of Ramadan fasting in case $0.27 (\pm 0.46)$ versus control $-0.02 (\pm 0.43)$ group ($P = 0.041$). Early increase in C3 level in cases (16.8 ± 17.49 vs. 2.3 ± 13.2 , $P = 0.006$) did not extend to the later stages of the study. On the other hand, ESR results demonstrated decrease in cases (16.4 ± 29.4 vs. 4.6 ± 23.9 , $P = 0.018$) in later stages of the study while no difference in ESR was detected in early phase of the study. Early increase in triglyceride in cases (6.1 ± 34.8 vs. 12.6 ± 25 , $P = 0.06$) did not continue during the later stage of the study. Ramadan fasting had no early effect on LDL, HDL and total cholesterol, but 3 months after Ramadan fasting, all of three items decreased in cases in comparison with control group. However, only cholesterol decreased in a significant fashion (16.4 ± 29.4 vs. 4.6 ± 23.9 , $P = 0.018$). HDL decreased in case $-3.9 (\pm 8.9)$ versus control $1.2 (\pm 7.5)$ group ($P = 0.059$) and LDL decreased in case $-10 (\pm 26.3)$ versus control $2.5 (\pm 17.5)$ group ($P = 0.088$).

There was no early or late statistically significant difference in other laboratory, clinical or quality of life variables including FUI, GPA and BMI between case and control groups. These data are summarized in (Table 1).

Irrespective of being in each group (after adding case to control group), a post hoc analysis about SF-36 showed early improvement of four dimensions despite no early or late difference between case and control group (Table 1). Those dimensions were bodily pain, emotional role limitation, vitality and general mental health. This improvement continued later in two of them including vitality and

general health perception. These data are summarized in (Table 2).

Discussion

The importance of this study is to determine the effect of Ramadan fasting on quiescent SLE. Allowing patients to practice fasting is a clinical challenge in Muslim community. Patients being fully capable of doing their religious acts will have a satisfactory effect and improve their quality of life.

Every exacerbating factor in SLE may induce disease flare-up. This flare-up may be accompanied with increasing anti-nuclear antibodies, especially anti-ds DNA, decreasing complements, especially C3 and moderately increasing inflammatory indices (ESR).

This study had four limitations. The first limitation was small sample size. The second was the selection of mild-to-moderate SLE patients. It was due to undetermined effect of fasting in SLE patients. As this was an unprecedented issue, uninvestigated in SLE cohort, we conducted this pilot study with limited number of patients who voluntarily participated. The third limitation was prednisolone dosage that was not recorded and compared between case and control groups before, immediately after and 3 months after Ramadan fasting. However, the dose of prednisolone was fixed during Ramadan fasting and 3 months thereafter without any adjustment in case or control group. The fourth limitation was calorie restriction and nutritional profile that were not recorded and compared between case and control groups throughout Ramadan. The objective of this study was to determine the effect of Ramadan fasting on mentioned variables, not the effect of calorie restriction amount and nutritional profile on them.

Despite the constant increase in anti-ds DNA, we had early increase in C3 and late decrease in ESR without any early or late change in SLE disease activity.

There is no similar study in the literature in human subjects, but in the study of Jolly [5] in mice which are prone to fatal autoimmune renal disease, lifelong 40 % dietary restriction in intake of all dietary components combined with substitution of fish oil for corn oil after 6 weeks of age resulted in 30 % delay in their kidney involvement and 42 % increase in their longevity.

Stable disease activity coupled with elevated anti-ds DNA could be due to low sample size of this study to show increase in disease activity, but early increase in C3 and delayed decrease in ESR in case relative to control group (although its P value is 0.077) could be an evidence of non-pathologic anti-ds DNA increment; however, other studies with larger sample size including more severe SLE patients

Table 1 Mean value of variables before, the day after and 3 months after Ramadan fasting in case and control groups and the *P* value of the differences of second to first then third to first visit after the comparison of case to control differences in each occasion in SLE patients in lupus unit of RRC in TUMS, Iran, in 2009

Variable	Case			Control			<i>P</i> value (2–1)	<i>P</i> value (3–1)
	First visit (mean ± SD)	Second visit (mean ± SD)	Third visit (mean ± SD)	First visit (mean ± SD)	Second visit (mean ± SD)	Third visit (mean ± SD)		
White blood cell (WBC)	7249 ± 2256	6929 ± 2485	7138 ± 2778	7339 ± 2701	6189 ± 2099	6511 ± 2205	0.15	0.24
Polymorphonuclear leukocyte	4650 ± 2132	4330 ± 2147	4020 ± 2171	4488 ± 1811	3721 ± 1533	4107 ± 1592	0.30	0.68
Lymphocyte	1822 ± 766	1788 ± 721	1835 ± 703	2034 ± 923	1712 ± 647	1793 ± 750	0.14	0.27
Hemoglobin	13.25 ± 1.04	13.01 ± 1.07	13.17 ± 1.1	13.48 ± 0.72	13.27 ± 0.94	13.54 ± 0.97	0.93	0.57
Platelet	257.4 ± 511.3	248.9 ± 499.2	261 ± 660.2	223.5 ± 665.4	224.3 ± 698.1	228.9 ± 632.1	0.20	0.89
Anti-ds DNA	0.83 ± 0.7	1.17 ± 0.94	1.12 ± 0.93	1.18 ± 1.54	1.25 ± 1.64	1.16 ± 1.31	0.026	0.041
C3	108 ± 26	124.8 ± 30.8	108.7 ± 23.6	107.3 ± 24.2	109.6 ± 26.4	105.3 ± 27	0.6	0.64
C4	19.8 ± 7.4	20.3 ± 7.4	18.1 ± 7.6	16.8 ± 8	16.5 ± 8.2	16.1 ± 9.6	0.34	0.37
CH50	100.8 ± 22.6	106.5 ± 28.9	97.4 ± 34.1	77 ± 34	83.6 ± 34.9	85 ± 43.1	0.9	0.22
ESR	19.9 ± 12	16.7 ± 14.6	14.6 ± 10.3	16.5 ± 13.1	16.1 ± 11.9	13.9 ± 12	0.26	0.077
Urine protein	0.19 ± 0.51	0.24 ± 0.54	0.14 ± 0.48	0	0.11 ± 0.32	0.16 ± 0.5	0.43	0.19
Urine red blood cell	0.05 ± 0.22	0.1 ± 0.3	0.05 ± 0.22	0.05 ± 0.23	0.05 ± 0.23	0.11 ± 0.32	0.57	0.55
Urine white blood cell	0.14 ± 0.36	0.57 ± 1.96	0.14 ± 0.36	0.05 ± 0.23	0.05 ± 0.23	0.05 ± 0.23	0.26	0.43
Urine granular cast	0	0	0	0	0	0	–	–
SLEDAI	2.14 ± 2.71	2.43 ± 3.25	2.62 ± 2.8	1.84 ± 1.83	1.79 ± 2.46	1.79 ± 2.32	0.71	0.55
Global physician assessment	0.19 ± 0.4	0.19 ± 0.4	0.24 ± 0.44	0.05 ± 0.23	0.11 ± 0.32	0.21 ± 0.54	0.53	0.62
Flare-up intensity	0.48 ± 0.51	0.29 ± 0.46	0.43 ± 0.51	0.32 ± 0.48	0.26 ± 0.45	0.32 ± 0.48	0.44	0.8
Body mass index	27.7 ± 4.2	27.1 ± 3.7	27.6 ± 3.7	26.3 ± 5.2	26.1 ± 5.4	26.5 ± 5	0.41	0.71
Triglyceride	104 ± 44.5	110.1 ± 45.3	99.5 ± 36.4	113.4 ± 47.2	100.8 ± 39.3	103.8 ± 45.5	0.06	0.67
Cholesterol	182.9 ± 32.4	174.8 ± 37	166.4 ± 40.7	182.5 ± 46.1	183.5 ± 36.4	187.1 ± 32.4	0.26	0.018
Low-density lipoprotein	105.2 ± 26.8	97.9 ± 28.7	95.2 ± 33.7	108.5 ± 30.4	108.8 ± 31.4	111.1 ± 27.6	0.26	0.88
High-density lipoprotein	56.5 ± 12.9	55.3 ± 11.3	52.7 ± 10.9	54.1 ± 11.8	53.1 ± 12.1	55.3 ± 10.3	0.94	0.059
<i>SF-36 Health Survey</i>								
Physical functioning	73.1 ± 25.7	72.92 ± 4.8	78.6 ± 20.7	74.2 ± 19.9	73.2 ± 21.8	75 ± 14.3	0.88	0.44
Physical role limitation	69 ± 39.5	66.7 ± 36.5	66.5 ± 38.3	67.1 ± 38.2	81.6 ± 32.1	65.8 ± 36.5	0.2	0.47
Bodily pain	69.7 ± 16.7	77.9 ± 14.8	69.1 ± 22.8	65.7 ± 20.1	74.3 ± 19.4	67.9 ± 21	0.95	0.69
Social functioning	74.4 ± 25.5	76.2 ± 24	67.3 ± 29.2	73 ± 24	84.2 ± 23.9	75 ± 25	0.2	0.33
General mental health	54.5 ± 19	68.2 ± 18.9	63.4 ± 18.9	55.2 ± 21.7	66.3 ± 21.2	59.2 ± 22.3	0.59	0.44
Emotional role limitation	54 ± 44	71.4 ± 32.1	58.7 ± 43.3	64.9 ± 40.8	80.7 ± 32	71.9 ± 31.9	0.61	0.88
Validity	55 ± 21.5	59.5 ± 18.5	61.9 ± 19.3	49.2 ± 16.8	56.8 ± 21.8	56.1 ± 20.8	0.59	0.99

Table 1 continued

Variable	Case			Control			P value (2–1)	P value (3–1)
	First visit (mean ± SD)	Second visit (mean ± SD)	Third visit (mean ± SD)	First visit (mean ± SD)	Second visit (mean ± SD)	Third visit (mean ± SD)		
General health perception	60.3 ± 17	66 ± 19.1	62.9 ± 17.7	63.6 ± 19.1	64.5 ± 13.7	69 ± 16.9	0.44	0.65

Unadjusted associations are depicted in bold italic and *P* values <0.1 are supposed to be statistically significant; WBC, polymorphonuclear leukocyte and lymphocyte (number per micro liter), hemoglobin (milligram per deciliter), platelet (×100 per micro liter), anti-ds DNA (anti-double-stranded deoxyribonucleic acid antibody; millimole per deciliter), C3 and C4 (the third and the fourth member of complement system; milligram/deciliter), CH50 (complement hemagglutination of 50; %), ESR (erythrocyte sedimentation rate; millimeter), urine protein (1+ to 4+), urine red blood cell, white blood cell and granular cast (number per high power field), SLEDAI (Systemic Lupus Erythematosus Disease Activity Index; 0–105), global physician assessment (0–3), flare-up intensity (1 and 2), triglyceride, cholesterol, low-density lipoprotein and high-density lipoprotein (milligram per deciliter), body mass index (kg/m²), SF-36 (Health Survey Short Form with 36 questions; %). Unadjusted associations are depicted in bold italic. *P* values <0.05 are supposed to be statistically significant

Table 2 Mean value of physical and mental dimensions of SF-36 Health Survey variables in (%) before, the day after and 3 months after Ramadan fasting in all patients irrespective of being in case or control group and the differences of second and third to first visit and comparison of them in either of two mentioned occasions in SLE patients in lupus unit of RRC in TUMS, Iran in 2009

Variable	First visit (mean ± SD in %)	Second visit (mean ± SD in %)	Third visit (mean ± SD in %)	P value (2–1)	P value (3–1)
Physical functioning	73.63 (±22.84)	73 (±23.12)	76.88 (±17.86)	0.81	0.28
Physical role limitation	68.13 (±38.39)	73.75 (±34.88)	65.63 (±36.99)	0.39	0.65
Bodily pain	67.8 (±18.26)	76.2 (±17.01)	68.55 (±21.68)	0.002	0.819
Social functioning	73.75 (±24.48)	80 (±23.99)	59.13 (±19.96)	0.09	0.54
General mental health	54.8 (±20.06)	67.3 (±19.76)	61.4 (±20.43)	<0.001	0.043
Emotional role limitation	59.17 (±42.36)	75.83 (±32.01)	65 (±38.45)	0.016	0.44
Vitality	52.25 (±19.38)	58.25 (±19.92)	59.13 (±19.96)	0.04	0.047
General health perception	61.88 (±17.90)	65.28 (±16.56)	65.8 (±17.39)	0.26	0.21

Unadjusted associations are depicted in bold italic. *P* values <0.1 are supposed to be statistically significant

are needed to prove the safety of Ramadan fasting in this group of patients.

The *P* value of early increase in TG and late decrease in LDL and HDL is between 0.05 and 0.1, but these results must be interpreted cautiously due to small sample size in our study. Unaltered BMI and early increase in TG may be due to decrease in meals to two a day but increasing the volume of each meal and consuming special pastries of Ramadan. Late statistically insignificant decrease in LDL and HDL eventuated in statistically significant late decrease in total cholesterol which all may be significant with respect to small sample size. There is no rational explanation for this unidirectional HDL and LDL decrease which could be real consequence of Ramadan fasting or be due to small sample size. Previous studies have addressed the changes in lipid profile during Ramadan [10–12]. In the study of Adlouni et al. [10], early decrease in BMI, TG, LDL and total cholesterol and increase in HDL cholesterol remained till one month after Ramadan fasting. In another study by Afrasiabi et al., fasting subjects showed temporary decrease in TG without any change in other lipid types

[10, 13]. These inconsistent data may be due to different number of studied population and varying nutritional customs in different Muslim countries. Iranian nutritional diet contains modest fat and fruit but high carbohydrate intake. Our results are compatible with a previous study by Azizi [14] which shows that TG level is related to the number of meals and the amount of calorie intake.

No difference between case and control group in SF-36 after Ramadan fasting may be real or due to small sample size or patients may be in remission. It may be due to a combining effect of fasting as a stressor and health satisfaction of being capable to fast as an ameliorating factor too [15]. A body of evidence has underlined the beneficial impact of fasting on mood enhancement and subjective feeling of well-being [16–18].

Early improvement in four dimensions of SF-36, namely bodily pain, emotional role limitation, vitality and general health perception were detected in both case and control groups. This improvement in vitality and general health perception remained till later stages of the study. The similar improvement in both groups may indicate a

fasting-independent factor. The spiritual effect of Ramadan month per se may play a partial role. However, this effect must be fully addressed by enrolling Muslims and non-Muslim patients in future studies.

This pilot study has no similar counterpart, and the most important advantage of this study is providing platform for future studies. Larger sample size studies including more severe patients are warranted to address the issue.

Conclusion

Despite the constant increase in anti-ds DNA, Ramadan fasting probably has no detrimental effect on SLE patients in quiescent phase of disease. Ramadan fasting may not affect these patients' quality of life. Ramadan fasting resulted in early decrease in triglyceride and late decrease in cholesterol, LDL and HDL.

Conflict of interest The authors would like to declare no potential conflicts of interest.

Ethical standard The study was conducted in accordance with instructions of the ethical committee in our academic center.

Informed consent All patients were asked to sign the informed consent form.

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