



Long-term Assessment of Fatigue in Patients with Culture-confirmed Lyme Disease

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ABSTRACT

BACKGROUND: Fatigue is a common symptom with numerous causes. Severe fatigue is thought to be an important manifestation of post-treatment Lyme disease syndrome. The frequency with which severe fatigue occurs as a long-term sequela in prospectively followed patients with Lyme disease is unknown.

METHODS: Patients with culture-confirmed Lyme disease who originally presented with erythema migrans have been evaluated annually in a prospective study to determine their long-term outcome. In 2011-2013, subjects were evaluated for fatigue using an 11-item Fatigue Severity Scale (FSS-11) that has been used in studies of post-treatment Lyme disease syndrome. An FSS-11 score of ≥ 4.0 is indicative of severe fatigue.

RESULTS: A total of 100 subjects were assessed, 52% of whom were male; the mean age was 64.9 years (range, 42-86 years). The mean duration of follow-up was 15.4 years (range, 11-20 years). Nine subjects had severe fatigue but in none as a consequence of Lyme disease. Only 3 subjects were thought to possibly have persistent fatigue from Lyme disease. The FSS-11 value for these 3 individuals was less than 4, averaging 2.27, and none had functional impairment.

CONCLUSIONS: Severe fatigue was found in 9 patients (9%) with culture-confirmed early Lyme disease at 11 to 20 years after presentation, but was due to causes other than Lyme disease. Fatigue of lesser severity was possibly due to Lyme disease, but was found in only 3% of 100 patients, and therefore is rarely a long-term complication of this infection.

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Authorship: All authors had access to the data and played a role in writing this manuscript.

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Fatigue is a common symptom with multiple causes, including infections.¹ Among US patients with early Lyme disease who present with the characteristic skin lesion erythema migrans, approximately 45% have fatigue concomitantly.² Fatigue also is thought of as a prominent symptom in some patients with Lyme disease who have residual symptoms despite antibiotic therapy and resolution of the objective manifestations of Lyme disease, such as erythema migrans.³ One of the placebo-controlled, double-blind, retreatment trials of patients with post-treatment Lyme disease syndrome exclusively enrolled patients with fatigue.⁴ The level of fatigue in that study was quantitated on the basis of an 11-item Fatigue Severity Scale (FSS) and a Visual Analogue Scale (VAS).

In the current study, we systematically evaluated 100 patients 11 to 20 years after the onset of early Lyme disease for fatigue using the same FSS-11 survey instrument that was used by other investigators who have studied

post-treatment Lyme disease syndrome.^{4,5} All of the patients in this study had the diagnosis of Lyme disease established by a positive culture for *Borrelia burgdorferi*.

MATERIALS AND METHODS

Adult patients with erythema migrans, for whom the diagnosis was confirmed by recovery of *B. burgdorferi* from culture of a skin or blood sample as previously described,⁶ have been systematically and extensively evaluated by interview and physical examination at baseline, at 6 months, at 12 months, and annually thereafter in a prospective study to determine the long-term outcome of this infection. Having an underlying illness was not an exclusion for participation in this study. Patients were treated with antibiotic regimens consistent with current guidelines.⁷ The study was conducted at the Lyme Disease Diagnostic Center of New York Medical College in Westchester County, New York, and was approved by the institutional review board of New York Medical College.

At all of the scheduled visits, the subjects were asked whether fatigue was present on that day; for those patients with fatigue, the duration was noted and the severity was quantitated using an 8-cm VAS, as previously described.⁶ The investigator made an assessment as to whether a cause for the fatigue was evident on the basis of interviewing and examining the subject; no diagnostic tests were performed to evaluate the complaint of fatigue. During the specific years of 2011 to 2013, those participants who returned to the study center were also assessed for fatigue by the FSS-11. The FSS-11 is a self-administered 11-item questionnaire about an individual's experience with fatigue over the prior 2 weeks, with each item scored on a scale of 1 to 7; the final score is the mean of the scores for each of the items. A score of ≥ 4.0 was considered to be indicative of severe fatigue, as previously reported.⁴

Subjects with fatigue at the time of visit in which the FSS-11 was performed were categorized as having post-Lyme disease fatigue if it began coincident with the onset of Lyme disease, lasted for at least 6 months during the first year after treatment, had no other known explanation other than having had Lyme disease, and persisted at least intermittently until the time of the visit in which the FSS-11 was performed.

Serologic Testing

At the visit in which the FSS-11 was performed, the C6 Lyme ELISA kit (Immunetics, Inc, Boston, Mass) was used according to the manufacturer's recommendations.

Statistical Methods

Categorical variables were compared using the Fisher exact test (2-tailed).

CLINICAL SIGNIFICANCE

- Severe fatigue was found in 9 (9%) of 100 patients with culture-confirmed early Lyme disease when assessed by an 11-item Fatigue Severity Scale at 11 to 20 years after presentation, but was due to causes other than Lyme disease.
- Fatigue of lesser severity, possibly due to Lyme disease, was found in 3% of the patients.
- Fatigue was rarely a long-term complication of early Lyme disease.

RESULTS

All 100 subjects with culture-confirmed Lyme disease who were able to be followed up from 2011 to 2013 underwent assessment for fatigue using the FSS-11 during their annual evaluation. One of these subjects was reassessed in 2014 when he developed a recurrence of erythema migrans.

The mean age of the 100 subjects was 64.9 years (range, 42-86 years) at the time of the FSS-11 assessment (Table 1), and 52.0% were male. When the FSS-11 was conducted, the mean duration of follow-up since the diagnosis of culture-confirmed Lyme disease was 15.4 years (range, 11-20 years). On the basis of a score of >0 on the fatigue VAS, 52 subjects (52.0%) had experienced fatigue at the baseline visit and 82 of 100 subjects (82.0%) experienced fatigue on at least 1 follow-up visit at ≥ 6 months after diagnosis. At least 24 (24%) of the patients experienced an additional episode of early Lyme disease (ie, the skin lesion, erythema migrans) during the follow-up period, and one third of these individuals experienced at least 2 subsequent episodes of erythema migrans.

Table 1 Characteristics of Patients with Culture-Confirmed Lyme Disease Who Were Evaluated by the 11-Item Fatigue Severity Scale 11 to 20 Years After Diagnosis and Treatment

| Characteristic | Finding |
|---|--------------|
| No. | 100 |
| % Male | 52.0 |
| Mean age in years (range) | 64.9 (42-86) |
| Mean duration of follow-up in years at time of FSS-11 (range) | 15.4 (11-20) |
| VAS fatigue score >0 at time of the FSS-11, no. (%) | 41 (41.0) |
| FSS-11 fatigue score ≥ 4.0 , no. (%) | 9 (9.0) |
| Fatigue present at baseline visit by VAS, no. (%) | 52 (52.0) |
| Multiple erythema migrans skin lesions at baseline, no. (%) | 19 (19.0) |
| Subsequent episodes of erythema migrans, no. (%) | 24 (24.0) |
| Reactive* C6 (Immunetics, Inc, Boston, Mass) serologic testing at FSS-11 visit, no. (%) | 42/99 (42.4) |

FSS-11 = Fatigue Severity Scale (maximum score 7.0); VAS = Visual Analogue Scale (8 cm long).

*Test result was positive or equivocal.

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