Lyme Disease Testing in Children in an Endemic Area

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ABSTRACT

Purpose: The purpose of this study was to determine clinician adherence to recommendations regarding diagnostic testing for Lyme disease (LD). The specific aims were to determine the rate of inappropriate test ordering for a diagnosis of erythema migrans and lack of confirmatory test ordering for positive LD screening tests.

Methods: Using the data warehouse of Marshfield Clinic Research Foundation's Bioinformatics Research Center, cases were identified from 2002 through 2007. A retrospective chart abstraction was performed using Marshfield Clinic's electronic medical record. The study involved children (<19 years old).

Results: In 57% of cases, LD testing occurred after a clinical diagnosis of erythema migrans was made. Patients with any symptom in addition to erythema migrans were more likely to have testing (odds ratio (OR) = 3.52, 1.75 - 7.08). A positive LD screening test was not confirmed 24% of the time. Lack of ordering confirmatory testing was not associated with any clinical factors or site of the evaluation.

Conclusion: This study found that some clinicians in an LD-endemic area do not follow guidelines for diagnosing children suspected to have Lyme disease.

INTRODUCTION

Just over 3 decades ago, Lyme disease (LD) was first recognized as a multi-system illness with an infectious etiology.[1] It is now the most commonly reported tick-borne infection in both North America and Europe.[2] During that time period, a practice guideline from the Infectious Disease Society of America (IDSA) was developed,[3] initially published in 2000, and then updated in 2006. LD practice management outlined in the *Red Book* is congruent with the IDSA practice guideline.[4] Though there remains much to be learned about LD, and some areas of management are not well established (eg, presentation with fever but without rash), most care for patients suspected of having LD is standardized.

Although an LD practice guideline has been available for a number of years, there has been an ongoing concern in the literature about LD management, especially related to diagnostic laboratory testing.[5-11] In a survey of New Hampshire clinicians, it was found that physicians seemed to rely on testing in situations in which it was unnecessary, including erythema migrans.[7] A survey of Wisconsin providers conducted by Ramsey et al,[6] assessing inappropriate testing with LD serologic tests, found that 27% of tests were inappropriately ordered, with a quarter of these for patients with erythema migrans. Qureshi et al,[8] in a prospective case series of children seen in a pediatric infectious disease clinic, noted a tendency for referring practitioners to treat based on a borderline LD screening test (LDST). This published literature is consistent with our clinical experience related to patient referrals.

This study was conducted in a health system that has an intranet guideline site for LD management that emphasizes the best-supported recommendations, with web links to primary source information. Two important recommendations are (1) that early LD manifested as erythema migrans is a clinical diagnosis for which serology testing is not recommended, and (2) when serologic testing is performed for evaluation of disseminated LD, a 2-tier process should be followed, with a confirmation of a positive LDST with a Western Blot LD confirmatory test (LDCT). In LD-endemic areas, patients presenting with erythema migrans-type rash have a relatively high likelihood of having LD. Seroconversion with a detectable antibody level is delayed, such that in most presentations laboratory testing

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will not assist in the diagnostic process, and the diagnosis is purely clinical. As for laboratory testing in disseminated LD in which a detectable antibody level is present, the simple enzyme immunoassay is used to initially screen patients due to the high sensitivity yet low cost of the test. LD enzyme immunoassay (EIA) tests have been limited by specificity so that confirmation with the more specific immunoblot technology is required.

We sought to determine how well clinicians within our health care system were following LD testing recommendations. We hypothesized that both inappropriate laboratory testing for erythema migrans was common, and that LD confirmatory testing for positive LD screening assays was not being performed consistently. Our specific aims were to determine how often clinicians inappropriately ordered LD testing after a diagnosis of erythema migrans was made clinically and how often clinicians failed to confirm a positive LDST with a LDCT. In contrast to previously published studies, we focused on the pediatric population and performed direct medical record abstraction rather than surveying clinicians.

METHODS

This study consisted of a retrospective chart review involving pediatric patients seen within the Marshfield Clinic System,(Marshfield, Wisconsin) from 2002 through 2007. Patients included in the study were children < 19 years old. This study was approved by the Marshfield Clinic Research Foundation's Institutional Review Board.

Using Marshfield Clinic's electronic medical record and data warehouse, potential cases were identified by appropriate International Classification of Diseases 9th Edition (ICD-9) codes (088.81 for Lyme disease and 795.79 for LDST) from 2002 through 2007.

Sample 1 included those patients diagnosed with LD, as there is no ICD-9 code specific to erythema migrans. Chart abstraction identified those patients who met the study case definition of a pediatric patient with erythema migrans (age < 19 years; clinician stated diagnosis of either erythema migrans, rash, or LD; or skin lesion described as being red or pink, at least 4 cm in size, and expanding with time). Patients who did not meet this definition were excluded. Patients with a rash not typical of erythema migrans were not included in the study. Chart abstraction was performed on the medical record of the cases that met these criteria. Data abstracted included clinician specialty, setting of the visit, subject date of birth and gender, history of specific tick bite or tick exposure, associated illness symptoms, and treatment.

Sample 2 included those patients who were found to have had a positive LDST. Chart abstraction was performed to confirm these were pediatric patients who met the case definition of having positive LDST for the first time (age < 19 years, a positive EIA or enzyme-linked immunosorbent assay [ELISA] serology test for *Borrelia burgdorferi* with no prior positive EIA, or ELISA serology test for *Borrelia burgdorferi*). Those who were diagnosed with erythema migrans were excluded (LDST should not have been ordered). Complete chart abstraction of the medical record for patients meeting the case definition was then performed. Data abstracted included clinician specialty, setting of the visit, subject date of birth and gender, history of specific tick bite or tick exposure, associated illness symp-

Table 1. Frequency Distribution of Clinical Characteristics for LDST

Clinical characteristic	No. of subjects	(%)
Rash of erythema migrans		
Yes	171	(71)
LDST ordered		
Yes	98	(57)
Type of location		
Emergency department	8	(5)
Urgent care	45	(26)
Primary care	85	(50)
Other	33	(19)
Duration of rash (days)		
<7	119	(70)
7-14	19	(11)
>14	10	(6)
Unknown	23	(13)
Exposure to tick(s)		
Yes	65	(38)
Tick bite		
Yes	32	(12)
Clinical symptoms/signs		
Yes	123	(72)
Fever		
Yes	74	(43)
Headache		
Yes	46	(27)
Weakness		
Yes	0	(0)
Fatigue		
Yes	41	(24)
Myalgia		
Yes	35	(20)
Chills		
Yes	7	(4)
Cranial nerve palsy		
Yes	3	(2)
Arthralgia/Arthritis		
Yes	33	(19)
Syncope		
Yes	0	(0)
Vomiting		
Yes	10	(6)
Gender		
Male	107	(63)
Female	64	(37)
Antibiotic		
Yes	171	(100)

Abbreviations = LDST, Lyme disease screening test.

Table 2. Odds Ratios (OR) and 95% Confidence Intervals (CI) for the status of Lyme Disease Screening Test (LDST) by Clinical Characteristics

Clinical characteristics	LDST Yes	LDST No	OR	CI	*P*-Value[b]
Type of location					
Emergency department/Urgent care[a]	30	23	1.00		
Primary care	46	39	0.90	0.45-1.80	0.77
Other	22	11	1.53	0.62-3.79	0.35
Duration of rash (days)					
<7[a]	78	64	1.00		
7-14	13	6	1.78	0.64-4.94	0.27
>14	7	3	1.91	0.48-7.70	0.36
Exposure to tick(s)					
Yes	37	28	0.98	0.53-1.84	1.00
No[a]	60	46	1.00		
Tick bite					
Yes	16	16	0.51	0.23-1.11	0.09
No[a]	92	47	1.00		
Clinical symptoms/signs					
Yes	81	42	3.52	1.75-7.08	<0.05
No[a]	17	31	1.00		
Fever					
Yes	48	26	0.91	0.48-1.70	0.76
No[a]	65	32	1.00		
Headache					
Yes	34	12	1.83	0.86-3.87	0.11
No[a]	76	49	1.00		
Fatigue					
Yes	28	13	1.18	0.56-2.50	0.66
No[a]	84	46	1.00		
Myalgia					
Yes	26	9	1.73	0.75-3.99	0.19
No[a]	85	51	1.00		
Arthralgia/Arthritis					
Yes	23	10	1.27	0.58-2.88	0.57
No[a]	89	49	1.00		
Male					
Yes	58	49	0.71	0.38-1.34	0.29
No[a]	40	24	1.00		
Age at diagnosis (years)			**1.05**	**0.98-1.12**	**0.18**
No. of subjects	**98**	**73**			
Mean	**8.9**	**7.9**			
Standard deviation	**4.5**	**4.7**			
Median	**8.2**	**7.0**			
Range	**1.0-18.8**	**0.6-18.0**			

[a] Referent group.

[b] *P*-value was derived from the unconditional logistic regression modeling.

toms—including the duration of illness—and clinical indication for ordering the LDST.

One author (BA) abstracted data from the medical record of the identified cases using specifically developed data abstraction forms. In situations where the data was equivocal, BA conferred with MH to reach consensus. Quality assurance was performed by trained abstractors from the Marshfield Epidemiology Research Center on 10% of the abstractions.

Statistical Analyses

The percent of inappropriate testing for LD and clinical characteristics of study patients are described and reported in the following Results section and tables. The association between each of the variables of interest (eg, gender, age, etc) and inappropriate testing for LD was assessed using unconditional logistic regression analysis with calculation of odds ratios (OR), 95% confidence intervals (CI), and *P*-values. A *P*-value of <.05 was used to claim that there exists a statistically significant association. All the data analyses were performed using SAS version 9.1 (SAS Institute, Cary, North Carolina).

RESULTS

Inappropriate Test Ordering for Erythema Migrans

The electronic data warehouse search identified 266 potential cases for the study period of 2002 through 2007 with 24 miscoded cases and 71 that did not have documentation of a rash consistent with erythema migrans. The remaining 171 erythema migrans cases underwent chart abstraction. The mean age of patients was 8.5 years, 63% were male. Of the 171 cases, 98 (57%) had LDST ordered, whereas 73 patients (43%) were managed without testing (Table 1). Half of the patients were seen in the primary care setting, and 30% were seen in an urgent care or emergency department setting. Most patients had the duration of the rash documented; 70% had the rash <7 days. Known tick exposure was documented in 49% of cases, with only 19% (32/171) having a known specific tick bite. Most of the patients had symptoms in addition to erythema migrans (72%), with fever (60%) being the most frequently reported. Treatment was started on all 171 cases; 2 had treatment delayed while awaiting serology. These 2 ultimately had negative serology.

Location of the clinical encounter, patient age or gender, duration of rash, tick exposure, and specific individual symptoms and signs were not associated with whether or not inappropriate LD testing was performed for erythema migrans.

However, patients with any additional clinical symptoms or signs, not just erythema migrans, were more likely to have testing (Table 2, OR=3.52 ordering LDST with the presence of symptoms/signs).

Failure to Confirm a Positive LDST with LDCT

The electronic data search for patients with a positive LDST identified 296 potential cases for the study period of 2002 through 2007. There were 109 cases excluded—98 due the presence of erythema migrans, 10 due a previous positive LDST (prior to the study period), and 1 in which there was no information in the reviewed record indicating that LDST was ordered. This left 187 patients for chart abstraction who had been evaluated for LD and had a positive LDST.

The mean age of patients was 10.3 years, 51% were male (Table 3). The majority of patients were seen in the primary care setting (62%). Duration of symptoms was 7 days or longer for half of the patients. The most common clinical reason for ordering testing was joint-related complaints. About a third of cases were patients being evaluated for fever with or without additional symptoms. There were only a few cases of classic disseminated LD such as cranial nerve palsy (4 patients).

Of the 187 patients with positive LDST, 45 (24%) did not have LDCT performed; 30 (67%) of these were treated. None of the clinical presenting factors or location of the evaluation were associated with appropriate confirmation of a positive LDST (Table 4).

Table 3. Lyme Disease – Frequency Distribution of Clinical Characteristics for Lyme Disease Screening Test (LDST)

Clinical Characteristic	No. of Subjects	(%)
Type of location		
Emergency department	13	(7)
Urgent care	22	(12)
Primary care	115	(62)
Other	37	(20)
Duration of symptoms (days)		
<7	85	(45)
7-14	24	(13)
>14	69	(37)
Unknown	9	(5)
Reason for ordering LDST: Suspected Lyme disease involving		
Skin	1	(1)
Joints	77	(41)
Nervous system	8	(4)
Skin/Joints	1	(1)
Joints/Other	3	(2)
Other	96	(52)
Clinical symptoms/signs		
Yes	176	(95)
Fever		
Yes	60	(32)
Headache		
Yes	54	(29)
Weakness		
Yes	3	(2)
Fatigue		
Yes	43	(23)
Myalgia		
Yes	41	(22)
Chills		
Yes	8	(4)
Cranial Nerve Palsy		
Yes	4	(2)
Arthralgia/Arthritis		
Yes	98	(52)
Syncope		
Yes	2	(1)
Vomiting		
Yes	18	(10)
Gender		
Male	96	(51)
Female	91	(49)
LDCT ordered		
Yes	142	(76)
No	45	(24)
Of the 45 LDCT not ordered—treated		
Yes	30	(67)
No	15	(33)

Abbreviations = LDCT, Lyme disease confirmatory test.

DISCUSSION

Our study findings are consistent with previous reports of a lack of clinician adherence with practice guidelines for LD management. Over half the patients presenting with erythema migrans had serology testing performed, even though there is no utility for serology in the evaluation of erythema migrans. The tendency to order serology to assist in the diagnosis of erythema migrans has been noted previously in surveys of providers.[7,9] Essentially one-fourth of the positive LDST did not have a confirmatory Western Blot performed as recommended by IDSA guidelines. Managing patients without performing LDCT has not been documented in the published literature.

For erythema migrans, part of the issue is likely the difficulty in making the clinical diagnosis.[5,12] No single clinical factor can be used to substantiate the diagnosis, and the skin lesion is not sufficiently characteristic as to be diagnostic. However, patients living in an endemic area who have a history of tick bite, systemic systems, and a rash suggestive of erythema migrans have a likelihood of LD that is clearly sufficient to justify treatment. For clinical presentations that are not as clear cut, other options exist, including observation for 24 to 36 hours to document an expanding skin lesion or referral to a dermatologist or infectious disease specialist with experience in LD evaluation. The important factor is that serologic testing (LDST) does not provide any clinical utility since most patients with erythema migrans have not developed a measurable immune response (seroconverted). The unneeded laboratory test adds to the health care cost.

Table 4. Odds Ratios (OR) and 95% Confidence Intervals (CI) for the status of Lyme Disease Screening Test (LDCT) by Clinical Variables

	LDCT				
Clinical Characteristics	**Yes**	**No**	**OR**	**CI**	***P*-Value[b]**
Type of Location					
Emergency department/Urgent care[a]	27	8	1.00		
Primary care	89	26	1.01	0.41-2.50	1.00
Other	26	11	0.70	0.24-2.02	0.51
Duration of rash (days)					
<7a	67	27	1.00		
7-14	17	7	0.98	0.37-2.63	0.97
>14	58	11	2.13	0.97-4.66	0.06
Suspected Lyme disease involving					
Skin/joint/nervous system	67	24	0.78	0.40-1.53	0.47
Othera	75	21	1.00		
Any Clinical Symptoms/signs					
Yes	134	42	1.37	0.34-5.52	0.66
No[a]	7	3	1.00		
Fever					
Yes	46	14	1.05	0.50-2.18	0.90
Noa	88	28	1.00		
Headache					
Yes	44	10	1.56	0.71-3.47	0.27
No[a]	90	32	1.00		
Fatigue					
Yes	34	9	1.25	0.54-2.87	0.60
No[a]	100	33	1.00		
Myalgia					
Yes	31	10	0.96	0.43-2.18	0.93
No[a]	103	32	1.00		
Arthralgia/Arthritis					
Yes	69	29	0.48	0.23-0.99	0.48
No[a]	65	13	1.00		
Vomiting					
Yes	14	4	1.11	0.34-3.57	0.86
No[a]	120	38	1.00		
Treated					
Yes	0	30	NA	NA	NA
No[a]	0	15			
Male					
Yes	69	27	0.63	0.32-1.25	0.18
No[a]	73	18	1.00		
Age at 1st lab test			**1.03**	**0.96-1.11**	**0.42**
No. of subjects	**142**	**45**			
Mean	**10.5**	**9.8**			
Standard deviation	**4.7**	**4.7**			
Median	**9.6**	**9.1**			
Range	**2.4-19.0**	**2.1-18.3**			

Abbreviation = LDCT, Lyme disease confirmatory test.

[a]Referent group.

[b]*P*-value was derived from the unconditional logistic regression modeling.

We speculated that testing might also delay treatment; however, only 2 patients had antibiotics held while waiting for test results. Both were treated after the testing returned negative. It is therefore quite difficult to understand why providers obtain serology testing when the diagnosis and treatment are completely independent of the test results.

Based on our clinical experience, our hypothesis was that clinicians would fail to confirm LDST on a routine basis. We found that clinicians failed to order confirmatory testing for positive LDST for almost a quarter of patients. Moreover, two-thirds of the patients with unconfirmed LDST were treated. The laboratory reporting in our health system includes a narrative recommendation for confirmatory testing without which less confirmatory testing may have occurred (although clinicians do have to place the order after the positive result because there is no reflex confirmatory testing). There are a number of issues related to using the screening test as the final diagnostic confirmation of LD, but a primary concern is missing or delaying the diagnosis of other important illnesses. Overuse of antibiotics also may occur.

Our study is limited due to its retrospective design; the clinical documentation occasionally lacked the detail desired for research review. One difficulty could be that some cases were not identified due to a clinician coding an illness other than LD (ie, rash). Additionally, this study represents the practice of providers in 1 geographic region from a single health system and may not be generalizable to practices elsewhere. Because this health system has an intranet guideline site covering LD management that clinicians have been asked to review, it could be suspected that the practice of these clinicians might be more in line with recommendations than providers in other settings.

An additional criticism of our study could be that the guideline recommendations for LD management are not as standardized as we state. We recognize that most practice guidelines (including IDSA's guideline for LD) have a significant component of expert opinion relative to a basis on clinical trials. But both management concerns reviewed in this study would not be addressed easily in a clinical trial, and there is little controversy as to whether either recommendation represents best practice

(erythema migrans being a clinical diagnosis and screening LD test requiring confirmation). Moreover, related to erythema migrans management, we only reviewed cases that were given a clinical diagnosis or had a rash documented in the medical record that was consistent with erythema migrans. The management of atypical rashes that could not be considered consistent with LD, for which management is not standardized, were not included in this study.

The literature addressing the issue of improving clinician practice to more closely match practice recommendations supports the use of simple guidelines that are well-supported by evidence with access via information technology.[13] This health system's intranet guideline site for LD management is based on the IDSA guideline with a bullet point outline for ease of use. Portals to various resources are available to facilitate access to further background information as needed. It is updated yearly with input from providers. However, there is no process in place to determine the impact of the site on clinical practice, and as demonstrated from the findings of this study, there is a need for practice improvement.

CONCLUSIONS

In managing patients with erythema migrans, clinicians were found to often rely on serology testing even though there is no clinical utility in doing so. Moreover, clinicians were also found to fail to perform the 2-step screening-confirmation testing for patients with positive LDST.

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Quiz: Lyme Disease Testing in Children in an Endemic Area

EDUCATIONAL OBJECTIVES

1. To understand the appropriate role of the Lyme Disease serologic tests and the Western Blot Lyme Disease confirmatory test in the management of patients suspected of having Lyme Disease.
2. To understand when treatment of Lyme Disease should be based on clinical signs alone.

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QUESTIONS

1. 4 cm or greater pink or red skin lesion that has expanded over time in a Lyme Disease endemic area is presumed to be erythema migrans, the skin lesion typical for Lyme Disease.
   - ❑ True
   - ❑ False

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2. When the clinical diagnosis of erythema migrans is made in a patient, the clinician should confirm the diagnosis of Lyme Disease by obtaining a Western Blot Lyme Disease confirmatory test prior to treatment.
   - ❑ True
   - ❑ False

3. In a patient with erythema migrans, seroconversion to give a positive Lyme Disease serologic test is often delayed.
   - ❑ True
   - ❑ False

4. In a patient suspected of having disseminated Lyme Disease, a positive Lyme Disease enzyme immunoassay (EIA) should be confirmed by a more specific Western Blot confirmatory test.
   - ❑ True
   - ❑ False

5. A Lyme Disease Western Blot test should be obtained only if the Lyme Disease screening serologic test is negative.
   - ❑ True
   - ❑ False

6. Patients living in an endemic area who have a history of a tick bite, systemic symptoms, and a rash suggestive of erythema migrans have a likelihood of Lyme Disease that is clearly sufficient to justify treatment.
   - ❑ True
   - ❑ False

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