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Original Research Article

To Determine the Seroprevalence and Demographic Pattern of Leptospira Infection in A Tertiary Care Hospital

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Abstract: ***Background***: A common zoonotic illness that has a major influence on public health, particularly in tropical areas, is leptospirosis. Because of its diverse clinical presentation, early and correct diagnosis is still difficult. Objectives: To ascertain the demographic distribution and sero-prevalence of leptospirosis in patients undergoing treatment at a tertiary care hospital. ***Methods***: A total of 619 suspected cases of leptospirosis were investigated using Rapid IgM Leptocheck, IgM ELISA, and PCR. There was a correlation between seropositive patients and demographic factors such age, gender, and occupation. The Chi-square test was used for statistical analysis. ***Results***: ELISA-based Seroprevalence in this cohort was 34.08%. PCR testing was conducted in 262 cases, of which 64 (24.42%) were positive. Among the seropositive cases, the highest number was in the 21–30 years and 31–40 years age groups, with 69 (32.7%) cases each. Males constituted 145 (68.7%) seropositive cases. The association between age, gender and ELISA sero positivity was statistically non-significant ($p>0.05$). Outdoor manual workers formed the largest group with 70 (33.17%) seropositive cases. Seasonal distribution showed clustering during the monsoon months. The majority of cases were diagnosed in August (53.55%), followed by July (31.75%), with a decline in September (5.21%). ***Conclusion***: Seroprevalence of leptospirosis, based on the positive result of ELISA test was 34.08%. Acute febrile sickness is still frequently caused by leptospirosis, especially in young adults and outdoor workers. The need for early diagnostic screening and increased clinical suspicion is highlighted by seasonal surges during the monsoon. To lower the burden of disease, community awareness, workplace safety, and preventive measures are crucial.

Keywords: Leptospirosis, Seroprevalence, IgM ELISA, PCR, Demographic Pattern.

INTRODUCTION

Leptospirosis is thought to be the most common zoonotic disease in the world. It mainly affects domestic and wild mammals, and humans can contract it by coming into direct touch with an infected animal or indirectly through polluted water or soil [1]. It is brought on by pathogenic Leptospira spirochetes. There are over 250 serovars in 25 Serogroups of the pathogenic L. interrogans. Despite being a global disease, leptospirosis has the most negative effects on human health in humid tropical nations. According to WHO estimations, leptospirosis incidence ranges from 0.1 to 1 case per 100,000 people annually in temperate, non-endemic areas and from 10 to 100 cases per 100,000 people annually in humid, tropical, endemic areas [2]. In high exposure risk groups and during outbreaks, the illness incidence is over 100 per 100,000 [3]. The incidence was estimated to be between 350,000 and 500,000 cases of severe leptospirosis per year based on data gathered worldwide by surveys conducted by the International Leptospirosis Society. More than 500,000 cases of leptospirosis are reported each year worldwide, according to the most recent

estimates [4]. The range of case-fatality rates is less than 5% to 30%. Since 1931, leptospirosis cases have been reported in India. Across the nation, leptospirosis is rapidly becoming to be a serious public health issue. According to numerous researches conducted in various parts of the nation, Seroprevalence rates vary from 6.4% to 37.7% [5]. Urbanization, poverty, and work-related conditions are examples of environmental factors that could lead to the disease's resurgence worldwide. Poor housing conditions, inadequate basic sanitation, and restricted access to healthcare and education—all of which are prevalent issues in developing nations—significantly raise the risk of human infection in urban environments [6]. Leptospirosis is one of the main causes of acute febrile sickness in the central and eastern regions of Uttar Pradesh, India [7]. It is also known as "mud fever" or "rice field fever."[8] The term refers to the spread of the disease, which occurs when people, primarily farmers, come into contact with tainted water. Living close to reservoir animals, high temperatures, rains, water logging, inadequate sanitation, and outdoor jobs are common epidemiological risk factors that promote the spread of disease [9]. The organism enters the host through the eye, mucosal surfaces, or skin abrasions. The incubation time is typically 10–12 days, but it can range from 3–30 days. The disease's clinical manifestations range from Weil's syndrome to serious, life-threatening consequences and subclinical infections. Fever, headache, myalgia, conjunctival suffusion, rash, hepato-splenomegaly, hemorrhagic symptoms, renal failure, Icterus, aseptic meningitis, ARDS, and pulmonary hemorrhage are among the clinical signs. [5]. Due to inadequate diagnostic facilities and setup, the disease is still under diagnosed in the majority of India's areas [10]. Microscopy, culture, and serological assays such as ELISA and MAT (Microscopic Agglutination Test) are typically used to make the diagnosis. Serogroups-specific, the gold standard test is the microscopic agglutination test (MAT). Nevertheless, live Leptospires are needed, and the performance is intricate. Consequently, a reference laboratory is always needed for this test. Genus-specific IgM ELISA is a suitable substitute serological test.

Aims & objectives: To study the Seroprevalence of Leptospira infection in clinically suspected patients, determine demographic pattern of leptospira infection and seasonal variation of leptospirosis admitted in tertiary care hospital.
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MATERIALS AND METHODS

This was a single centric, observational prospective study conducted in Department of Microbiology of a tertiary care, teaching hospital, from January, 2016 to December, 2016 (one year).

Inclusion criteria

1. Febrile patient presenting with sign- symptoms suggestive of leptospirosis
2. Patients willing to give written inform consent to participate in the study

Exclusion criteria

1. Patient not willing to give written inform consent
2. If complete History and adequate data not available from patient

A total of 619 cases fulfilled the inclusion criteria were selected for the study. A detailed history including the demographic profile, past history and risk factors were elicited for each patient and duly recorded in the case record form. Consent was taken from each patient for participation in the study after explaining the protocol.

Sample collection: About 5 ml of blood was collected from clinically suspected leptospira patients in a sterile vacationer. Serum was separated as soon as possible by centrifugation at 2000 rpm for 15 minutes. The serum samples were preserved in sterile vials at -20°C and testing was carried out at the end of every month
The working definition of a ''suspected'' case of leptospirosis for inclusion into the present study was ''who had presented to our hospital with a history of abrupt onset of high fever, and the fever was documented to be more than 39°C at the time of presentation''. As a screening test in every patient with ''suspected leptospirosis'', Rapid IgM Leptocheck test detection assay was performed. Also in every patient, anti Leptospira IgM antibodies were quantitatively estimated using an IgM anti-leptospiral enzyme linked immunosorbent assay (ELISA), which will be further referred to as the IgM-ELISA test. Polymerase chain reaction (PCR) tests were done in cases that were negative for IgM Leptocheck and ELISA.

Statistical method: Data was collected and compiled in Microsoft Office Excel version 2013 and a descriptive statistical analysis was carried out. Data was presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, means and standard deviations for quantitative variables. Qualitative variables were compared using ($\chi 2$) test while (t) test will be used for comparison of quantitative data. Statistical significance will be considered at p-value ≤ 0.05.

RESULT

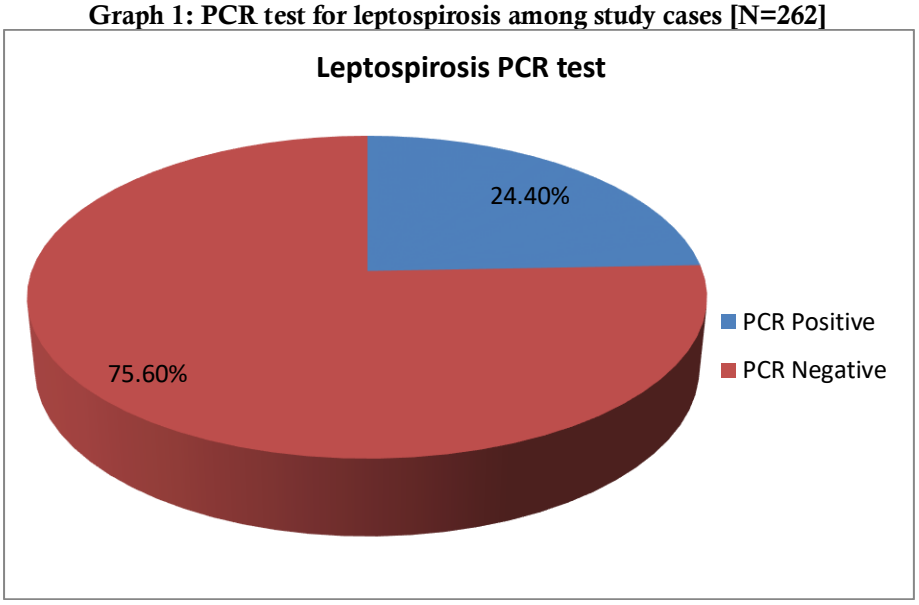
Out of 619 suspected cases, Rapid IgM Leptocheck test was positive in 230 (37.15%) cases, whereas IgM ELISA showed positivity in 211 (34.08%) cases. Thus, ELISA-based Seroprevalence in this cohort was 34.08%.

Table 1: Test for leptospirosis among study cases [N=619]

Test	Positive	Negative
Rapid IgM Leptocheck (619)	230 (37.15%)	389 (62.84%)
ELISA (619)	211 (34.08%)	408 (65.91%)

PCR testing was conducted in 262 cases, of which 64 (24.42%) were positive while 198 (75.57%) were negative. This indicates a relatively lower positivity compared to serological tests, reflecting detection mainly in acute infection.

Graph 1: PCR test for leptospirosis among study cases [N=262]



Among the seropositive cases, the highest number was in the 21–30 years and 31–40 years age groups, with 69 (32.70%) cases each. The 41–50 years group accounted for 54 (25.59%) cases, while the ≤20 year's group had only 6 (2.84%) cases. Very few cases (13; 6.16%) were recorded in the 51–60 years group, and none above 60 years. Males constituted 145 (68.7%) seropositive cases and females 66 (31.3%).

Table 2: Age and Gender wise distribution of seropositive cases [N=211]

Age (Year)	Male	Female	Total seropositive	Percentage (%)
≤10	3	-	3	1.42%
11-20	2	1	3	1.42%
21-30	46	23	69	32.70%
31-40	48	21	69	32.70%
41-50	36	18	54	25.59%
51-60	10	3	13	6.16%
≥61	-	-	-	-

On statistical analysis, ELISA positivity was 22.2% in ≤20 years, 34.8% in 21–40 years, 34.7% in 41–60 years, and 0% above 60 years. The association between age and ELISA sero positivity was statistically non-significant (χ^2 = 2.840, p = 0.417).

Table 3: Correlating age with cases tested for Sero positivity with ELISA

		ELISA	
		Positive	Negative
Age	≤20	6 (22.2%)	21 (77.8%)
	21-40	138 (34.8%)	259 (65.2%)
	41-60	67 (34.7%)	126 (65.3%)

	>60	0 (0.0%)	2 (100%)

X chi square=2.840, df=3, p value=0.417, non significant

Table 4: Correlating gender with cases tested for Sero positivity with ELISA

		ELISA	
		Positive	**Negative**
Sex	Female	66 (33.5%)	131 (66.5%)
	Male	145 (34.4%)	277 (65.6%)

Chi square=0.044, df=1, p value=0.834, non significant

Among 211 ELISA-positive cases, 145 (34.4%) were males and 66 (33.5%) were females. The gender difference in positivity was statistically non-significant ($\chi^2 = 0.044$, $p = 0.834$).

Table 5: Occupation wise distribution [N=211]

Occupation	Seropositive cases	Percentage (%)
Outdoor manual worker	70	33.17%
Outdoor non manual worker	58	27.50%
Students	62	29.38%
House wife	6	2.84%
Unemployed	6	2.84%
Retired	4	1.89%
Unknown	4	1.89%

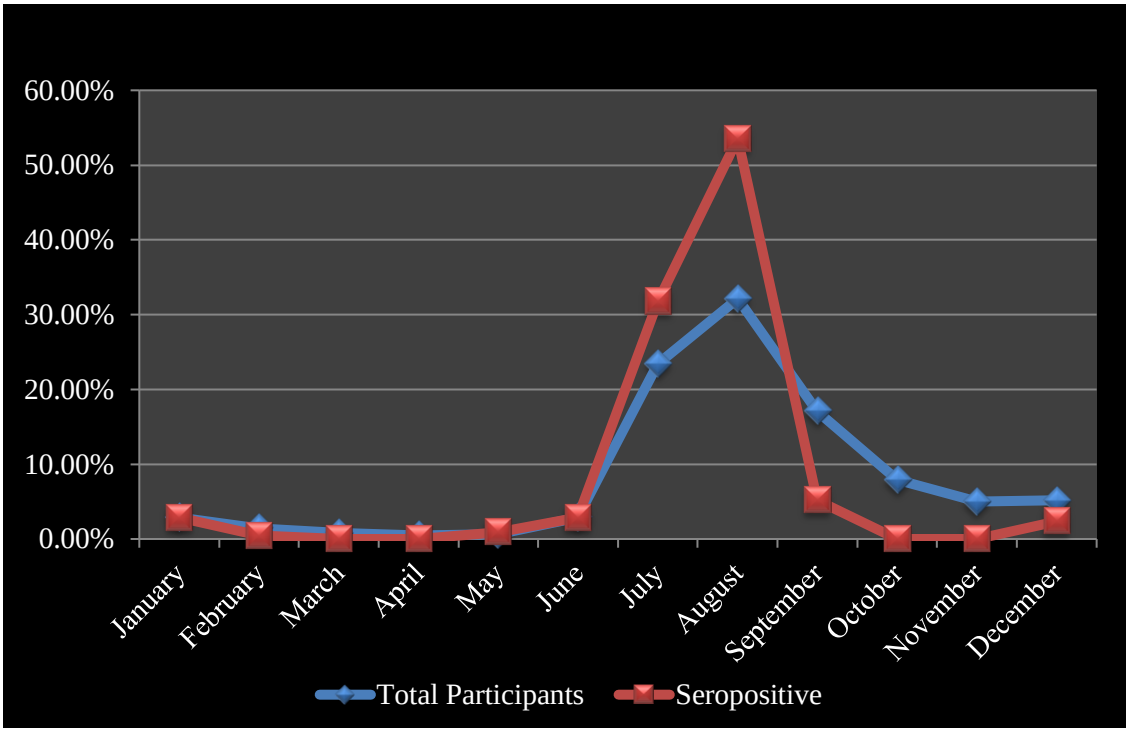
Outdoor manual workers formed the largest group with 70 (33.17%) seropositive cases, followed by students 62 (29.38%) and outdoor non-manual workers 58 (27.50%). Housewives, unemployed, and retired individuals each contributed less than 3% of cases.

Table 6: Leptospirosis cases among study cases

Test	ELISA Positive	ELISA Negative	P value
RAPID IgM Leptocheck Positive	204 (32.95%)	26 (4.20%)	<0.001
RAPID IgM Leptocheck Negative	7 (1.13%)	382 (61.71%)	

Out of total cases, 204 (32.95%) were positive by both ELISA and Rapid test, while 382 (61.71%) were negative by both methods. Discordance was noted in 26 (4.20%) cases which were Rapid-positive but ELISA-negative, and 7 (1.13%) which were ELISA-positive but Rapid-negative. The correlation was statistically highly significant ($p < 0.001$).

Graph 2: Month wise distribution of seropositive cases



Seasonal distribution showed clustering during the monsoon months. The majority of cases were diagnosed in August (53.55%), followed by July (31.75%), with a decline in September (5.21%).

DISCUSSION

Leptospirosis is a widespread zoonotic disease and humans are accidental host. It is also known as 'Great Mimicker' as it is often indistinguishable from other acute febrile illness including dengue, typhoid, and others. Severe leptospirosis infections may lead to multiple organ failure such as renal failure, hepatic dysfunction, cardiac and pulmonary complications. Serological test is the test most commonly used to diagnose leptospirosis due to difficulty in its isolation, lack of sensitivity and specificity in dark field microscopy in laboratory diagnosis of leptospirosis [11]. Seroprevalence of leptospirosis in our study was 34.08 %, based on positive results of ELISA, Almost similar results were reported by two studies conducted by Karande et al [12] and De et al [13] where sero-prevalence was 34 % and 36.27% with IgM- ELISA test respectively and in Assam by Dwijen Das, et al [14] where sero-prevalence was reported 38 % by ELISA. The higher specificity, sensitivity, PPV and NPV of IgM ELISA suggest that IgM ELISA is appropriate for confirmation and definitive diagnosis.

PCR was positive in 24.42% cases in the present study. PCR detects DNA while other tests detect antibody in sera so, PCR is an effective complementary test in the first phase of the disease, particularly when no specific antibodies were detected in serological reaction and helps in detection of more cases which would have been missed by antibody test and hence was done in cases negative with Rapid Leptocheck and ELISA, in agreement with the studies conducted by Ooteman et al [15] and Brown et al [16] showed prevalence of leptospirosis by PCR as 13-29% and 21.12% respectively.

Among the seropositive cases, Majority of the cases were young adults belonging to the age group of 21-40 years with average age being 35.46 ±10.22 years. This was in accordance with the Regmi et al [17] and Mansoor et al [18] where young adult were affected most commonly and the average age was 36.4 year and 32.6 years respectively. Young adults are the active population involved in outdoor activities and recreational activities and hence an increased chance of exposure to infection.

Males were affected more in comparison to females in current study. Male preponderance was seen in comparable to studies conducted by Vijayalakshmi, et al [19] and A Krishnamurthy, et al [20].There is an excess of male leptospirosis cases reported from India, a pattern traditionally linked to their greater occupational exposure.

Among seasonal distribution, majority of the cases were seen between July to September. Our results correlate with the Baveja B, et al [21] and Mansoor et al [18]. This increase incidence in monsoon can be due to flooding, water stagnation and polluted environment. Flooding after heavy rains is particularly favorable to leptospirosis. It prevents animal urine from being absorbed into the soil or evaporating, so leptospira pass directly into the surface waters or persist in mud.

Occupation wise distribution among seropositive cases in our study showed, outdoor manual worker followed by students, were seropositive for leptospirosis, consistent findings were seen in studies conducted by Saha et al [22] and Goyal et al [23] where more than 50 % of outdoor worker were seropositive for leptospirosis. This establishes

the fact that persons who are more exposed to contaminated environment are at a higher risk of contracting the disease, since work related activities are frequently identified as risk exposures, it is considered as an occupational disease.

CONCLUSION

The sero-prevalence of leptospirosis, based on the positive result of ELISA test was 34.08%. In northern India, leptospirosis remains a serious health issue, especially during the monsoon season. Young adult males and those working outdoors are the disease's main targets. Although ELISA should continue to be the confirmatory test, rapid IgM assays offer a trustworthy screening method. Reducing illness incidence requires enhancing surveillance, expanding access to diagnostics, and putting preventive measures in place, such as better sanitation and worker protection gear.

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