e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2023; 15(12); 310-316

Original Research Article

A Study of the Correlation of PANBIO Unit with Biochemical and Haematological Parameters of Laboratory-Confirmed Leptospirosis Cases in Tertiary Care Centre in Dadra and Nagar Haveli

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Received: 11-07-2023 Revised: 20-08-2023 / Accepted: 25-09-2023
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Conflict of interest: Nil

Abstract

Background: Leptospirosis, an infection caused by the spirochete Leptospira interrogans, is a neglected tropical illness. It is one of the disorders that must be reported. It is often misdiagnosed or not identified in India and other tropical nations. This research aims to establish a relationship between Panbiounit and biochemical and haematological markers in laboratory-confirmed leptospirosis patients.

Material and Methods: This observational research was done from July 2019 to November 2020 at the microbiology department of a tertiary care hospital and included 80 clinically suspected and diagnosed cases of leptospirosis. Using Epi info version 7 software, socio-demographic, biochemical, and haematological data were researched and evaluated.

Results: In the present study, the participants' mean age was 38.8 ± 17.1 years. Among them, 53 (66.25%) were male while 27 (33.75%) were females, 31 (38.75%) were B positive, 24 (30.00%) were O positive, 20 (25.00%) were A positive and 05 (6.25%) were A.B. positive. HbS Antigen was reactive among 02 (2.5%) patients, while it was Non-reactive in 78 (97.5%) patients. Leptospirosis patients had significant anaemia, leucocytosis, and elevated liver and renal parameters. In the present study, there was a significant Correlation of the Pan Bio Index with Serum potassium (r=0.23, p-value 0.04), Serum Creatinine (r=0.38, p-value 0.001) and BUN (r=0.27, p-value 0.017).

Conclusion: When someone presents with fever and jaundice, leptospirosis is a significant possibility in D.N.H region. Haematological abnormalities in leptospirosis patients included anaemia, leukocytosis, increased liver, and high renal parameters. There was a strong correlation between the Pan Bio Index and serum potassium, serum creatinine, and blood urea nitrogen.which indicate the severity of leptospirosis & On the basis of liver and renal functions, a hospital can develop its own clinical algorithm to suspect the case of leptospirosis.

Keywords: Biochemical and haematological Parameters, leptospirosis

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Introduction

Leptospirosis is predominantly a zoonotic disease, although humans act as unintentional hosts. Leptospirosis is an infection caused by the Leptospiraceae family's pathogenic Leptospira. The principal sources of infection are rats, cattle, and other animals, which may spread the illness to people via skin wounds or breaks and mucous membranes. The illness may be spread by direct contact with an infected animal or by indirect contact with soil or water contaminated with urine. Leptospirosis is characterized by high fever, headache, muscular discomfort, chills, red eyes, and a rash, which may proceed to more severe illnesses Including renal failure, liver damage, and death. [1-4]

Leptospirosis is common in many climates, from tropical to subtropical to temperate. The disease is widespread in the Indian states of Maharashtra, Karnataka, Kerala, Tamil Nadu, and the Andaman and Nicobar Islands while underreported in less developed nations. The World Health Organization reports that in countries where the disease is common, people tend to downplay the problem because they do not realize how widespread it is. [5-6]

Leptospirosis is a serious public health concern in Gujarat, India and is particularly prevalent in rural and semi-urban areas, where poor sanitation and inadequate waste management practices increase the risk of exposure to contaminated water and soil. In addition, the state's high population density, lack of access to clean water, and insufficient public health infrastructure exacerbate the spread of leptospirosis and make it difficult for those infected to receive timely and effective treatment. The economicburden of the disease also affects the state, leading to decreased productivity and increased healthcare costs. [6-7]

The trend of leptospirosis cases in Gujarat, India, is not well documented due to underreporting and a lack of surveillance systems, but the incidence of the disease is known to be high in some areas of the state. Nevertheless, continued monitoring and research are crucial to understand the epidemiology of leptospirosis in the state and develop effective interventions to prevent and control the disease. To address the problem of leptospirosis in Gujarat, there is a need for effective interventions that target the underlying causes of the disease, such as improving sanitation and waste management practices, increasing access to clean water, and strengthening the public health infrastructure. In addition, efforts must be made to raise awareness of the disease, educate the public on reducing their risk of infection, and provide access to early diagnosis and treatment for those affected. [8-11]

The Pan Bio Unit is a quick and reliable diagnostic tool for leptospirosis, and it is widely used in both developed and developing countries. The "Pan Bio Unit" is likely a reference to a diagnostic test for leptospirosis produced by Panbio. Panbio is a manufacturer of diagnostic tests for a variety of infectious diseases, including leptospirosis. The Pan Bio Unit is an enzyme-linked immunosorbent assay (ELISA) used to detect antibodies against Leptospira in the blood. The test works by using a panel of antigens representing different strains of Leptospira, and it is designed to detect a wide range of antibodies specific to different types of leptospirosis. However, like all diagnostic tests, it has limitations, and a positive result should be confirmed by additional testing, such as PCR or culture. Although the Pan Bio Unit is a valuable tool for the diagnosis of leptospirosis, it should be interpreted in conjunction with other clinical and laboratory findings to arrive at a definitive diagnosis. [12,13]

Aims & Objectives

To correlate panbiounit with biochemical and haematological parameters of laboratory-confirmed leptospirosis cases in the tertiary care centre in D.N.H.

Materials and Methods

Study Setting, Time and Duration: This observational study was conducted in the tertiary care hospital microbiology department from July 2019 to November 2020.

Study Participants: This study investigated and confirmed eighty instances of leptospirosis. All P.U.O. instances that occurred while the research was being conducted were analyzed. Rapid negative samples were not included. The V.B.C.H. has evaluated every instance of Pyrexia of Unknown Origin (P.U.O.) using a quick card test based on immunochromatography, a novel TWO-SITE immunoassay on a membrane (LEPTOCHECK ZYPHER INC.). The anti-human IgM colloidal gold conjugate creates a complex with IgM antibodies in the test sample when the sample passes across the membrane assembly of the testing device. As this complex reaches the test window 'T,' it becomes immobilized by the widely reactive leptospira genus-specific antigen coated on the membrane, creating a band ranging from red to deep purple at the test area. T, denoting a successful diagnostic procedure. Using a quick card screen, IgM ELISA was used to confirm all positive samples. Any samples that test positive for leptospirosis using the ELISA IgM assay are considered positive.

Study Measurements: Socio-demographic information, history of Clinical signs and symptoms and complications were collected from all enrolled patients. Biochemical parameters (liver function tests, renal function tests, serum electrolytes) were tested by a fully automated biochemistry analyzer (xpandplu and semen inc). All haematological parameters (Hb, WBC count and platelet count)were tested by 3 part nihonkohden haematological analyzer. U.S.G. abdomen pelvis was recorded at the time of admission.

Statistical Analysis: Individual patient data matching the inclusion and exclusion criteria were extracted from their respective files, imported into Microsoft Excel, and analyzed using Epi info version 7 software. The demographic information was classified according to frequency, whilst the haematological and biochemical data were computed to provide a mean and standard deviation.

Result

The present study includes 80 clinically suspected and diagnosed leptospirosis cases. The mean age of the study participants was 38.8 ± 17.1 years. Among them, 53 (66.25%) were male while 27 (33.75%) were females, 31 (38.75%) were B positive, 24 (30.00%) were O positive, 20 (25.00%) were A positive and 05 (6.25%) were AB positive. HbS Antigen was reactive among 02 (2.5%) patients, while it was Non-reactive in 78 (97.5%) patients. (Table-1)

Table 1: Characteristics of study participants

Variables	
Age (years)	38.8 ± 17.1
Gender	
Male	53 (66.25%)
Female	27 (33.75%)
Blood groups	
B Positive	31 (38.75%)
O positive	24 (30.00%)
A positive	20 (25.00%)
AB positive	05 (6.25%)
HbS Antigen	
Non-reactive	78 (97.5%)
Reactive	02 (2.5%)

Among the patients, the mean Hemoglobin (g/dl) was 9.74± 2.65, mean T.L.C. (per cu mm) was 12.71± 7.41, mean R.B.C. (per cu mm) was 3.74±0.86, mean PCV (%) was 33.44±39.141, mean MCV (femtoliter) was 78.46±11.99, mean M.C.H. (picograms/cell) was 27.10±6.20, mean M.C.H.C. (gm/dl) was 33.32±2.41, mean Polymorphs was 76.61±11.66, mean Lymphocytes was 19.15±10.94, mean Eosinophils was 2.03±0.87, mean Monocytes was 2.05± 1.1 and mean Basophils was 0.0±0.0. (Table-2)

Table 2: Hemogram of study participants

Hemogram	**Mean**	**SD**
Haemoglobin (g/dl)	9.74	2.65
TLC (per cu mm)	12.71	7.41
RBC (per cu mm)	3.74	0.86
PCV (%)	33.44	39.141
MCV (femtoliter)	78.46	11.99
MCH (picograms/cell)	27.10	6.20
MCHC (gm/dl)	33.32	2.41
Polymorphs	76.61	11.66
Lymphocytes	19.15	10.94
Eosinophils	2.03	0.87
Monocytes	2.05	1.1
Basophils	0.0	0.0

Among the study participants, the mean total bilirubin (g/dl) was 8.85± 8.47, mean Directbilirubin (g/dl) was 7.46±7.53, mean Indirect bilirubin (g/dl) was 2.14± 4.81, mean S.G.P.T (A.L.T.) (U/L) was 85.72± 117.89, mean Alkaline phosphatase (U/L) was 103.29±53.71, mean S.G.O.T (A.S.T.) (U/L) was 154.33± 281.58,
mean Albumin-globulin Ratio was 3.73±27.11, mean Serum sodium (mEq/L) was 125.46± 32.03, mean Serum potassium (mEq/L) was 4.71±5.26, mean Serum Chloride (mEq/L) was 97.53±7.40, mean Serum Creatinine (mg/dl) was 3.42 ±2.48, mean Blood urea nitrogen (mEq/L) was 65.83± 40.07, mean Random blood sugar (mg/dl) was 127.82± 86.10 and mean Pan Bio Unit was 26.69±5.86.(Table-3)

Table 3: Blood investigations among study participants

Blood test	**Mean**	**SD**
Total Bilirubin (g/dl)	8.85	8.47
Direct bilirubin (g/dl)	7.46	7.53
Indirect bilirubin (g/dl)	2.14	4.81
S.G.P.T (A.L.T.) (U/L)	85.72	117.89
Alkaline phosphatase (U/L)	103.29	53.71
S.G.O.T (A.S.T.) (U/L)	154.33	281.58
Albumin-globulin Ratio	3.73	27.11
Serum sodium (mEq/L)	125.46	32.03
Serum potassium (mEq/L)	4.71	5.26
Serum Chloride (mEq/L)	97.53	7.40
Serum Creatinine (mg/dl)	3.42	2.48
Blood urea nitrogen (mEq/L)	65.83	40.07
Random blood sugar (mg/dl)	127.82	86.10
Pan Bio Unit	26.69	5.86

In the present study, there was a significant Correlation of the Pan Bio Index with Serum potassium (r=0.23, p-value 0.04), Serum Creatinine (r=0.38, p-value 0.001) and BUN (r=0.27, p-value 0.017). At the same time, there was no significant Correlation of the Pan Bio Index with S.G.P.T, Alkaline phosphatase, S.G.O.T, Albumin-globulin Ratio, Serum sodium and Serum Chloride.(Table-4)

Table 4: Correlation of Pan Bio Index with other blood parameters

	Pearson Correlation coefficient	p-value
S.G.P.T	-0.09	0.44
Alkaline phosphatase	0.08	0.5
S.G.O.T	-0.16	0.16
Albumin-globulin Ratio	-0.16	0.16
Serum sodium	-0.03	0.8
Serum potassium	0.23	0.04
Serum Chloride	-0.13	0.25
Serum Creatinine	0.38	0.001
BUN	0.27	0.017

Discussion

Patients with fever in tropical and subtropical regions should be evaluated for leptospirosis as a possible cause. Patients may have symptoms similar to or identical to those of other tropical illnesses. Weil's illness is characterized by a range of hematological and biochemical abnormalities, from moderate to severe. [14,15]

Here we used panbio Elisa to find out the positive cases of leptospirosis. This test relies on the detection of IgM antibodies which appear in the blood a day or so earlier than those used in MAT. There is often poor correlation between MAT and ELISA results on sera of individuals. The reference standard is MAT, IgM antibodies become detectable during the first week of illness, allowing the diagnosis to be confirmed and treatment initiated while it is likely to be most effective though, antibody levels are generally low or absent during very early infection [26,27]. Though Microscopic agglutination test is considered to be the gold standard in the diagnosis of leptospirosis, its use as a routine diagnostic test in a clinical laboratory is limited. The test is both complex and tedious for routine use. Many studies have demonstrated Pan Bio ELISA to be more sensitive than MAT for detection of cases early in acute illness [2]. IgM antibodies start appearing during the first week of illness though antibody levels are low or not detectable very early on in the illness. Leptospirosis can be diagnosed on the basis of the presence of IgM antibodies by Pan Bio ELISA, in a single serum sample collected during the acute phase of the illness. A convalescent sample taken after two weeks is required to confirm the results. A limitation of using a single serum sample in the demonstration of IgM antibodies is the absence of antibodies very early on in the infection or the persistence of antibodies. IgM antibodies in leptospirosis persist for a long period with varying rates of decline [28]. A single serum sample taken during an acute febrile illness with symptoms of leptospirosis is presumptive evidence of infection, and therefore requires confirmation by further testing.so in resource limited setup correlation with other biochemical and Haemtological is required.

Leptospirosis, one of the neglected tropical illnesses, is on the rise again. It poses a threat to public health on a worldwide scale. In the present study, most patients affected were male (66.25%), while 27 (33.75%) were females. Similarly, males were outnumbered by females in the studies done by George T et al. [15], Kaur P et al. [16] and Becirovic A et al. [17]. Mean age of our study participants was 38.8 ± 17.1 years which is similar to studies done by George T et al. [15], D. B. Zala et al. [18] and Kaur P et al. [16] This suggests that men are more likely to get Leptospirosis than women and that the disease mostly affects those of working age.

In the current study, the haematological and biochemical parameters among the patients with leptospirosis were grossly deranged. The patients had severe anaemia, leucocytosis, neutrophilia and monocytosis. Similar findings were observed in various studies done across the globe. [18-20] Serum total bilirubin, glutamate oxaloacetate transaminase, and glutamate pyruvate transaminase were the most affected liver function tests (LFTs). Equally elevated were markers of renal function, such as blood urea and serum creatinine. Manyinvestigations, including ours, have found hepatic and renal impairment in hospitalized patients with leptospirosis. [21-25]

Differential diagnosis of leptospirosis and establishing a fast diagnosis are crucial in everyday practice, particularly in mysterious febrile illnesses. This is essential for prompt and effective treatment, lowering the risk of complications and death. One of the most effective ways to stop the spread of leptospirosis is through public health education. [26-28]

Limitation: Smaller sample size may explain the statistically insignificant neutrophilia and lymphopenia. Studies involving larger sample size may throw a light onto this aspect.

Conclusion

Males presenting with fever and jaundice should raise a high suspicion for leptospirosis. Haematological alterations in leptospirosis patients included anaemia, leukocytosis, and increased liver and renal parameters. Potassium Serum, Creatinine Serum, and BUN strongly correlated with the Pan Bio Index. Thus, it was concluded that the abnormal liver and renal function may be considered as an indicatorof suspicious case of leptospirosis in highly endemic region and on the basis of elevation of abnormality in the liver and renal functions of suspected case, a hospital can develop their own clinical algorithm towards the confirmation of leptospirosis.

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