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Prevalence of *Helicobacter pylori* infection and associated risk factors among patients with active pulmonary tuberculosis and healthy controls in Northwest Ethiopia

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ABSTRACT: ***Helicobacter pylori*** **remains a major public health problem and the burden of infection is more pronounced in the resource-limited countries including Ethiopia. The** ***tuberculosis*** **(*tb*) is also the most prevalent infectious diseases, especially in low income settings. To date, the association between** ***Helicobacter pylori*** **and** ***Mycobacterium tuberculosis infection*** **is controversial. Thus, this study aimed to determine the prevalence and associated factors of** ***H. pylori*** **infection among TB patients and apparently healthy controls. To assess the prevalence and associated risk factors of** ***H. pylori*** **infection among patient with active pulmonary tuberculosis and healthy controls. A comparative cross-sectional study was conducted at Gondar university hospital, Debark Hospital, kolladiba HC, sanja HC and HCs found in Gondar town from February to May 2017. A convenient sampling technique was carried out to enroll 120 known active pulmonary tuberculosis patients and the same number of apparently healthy controls. A structured questionnaire was used to collect data. Approximately three grams of stool sample were collected, which is aimed to assess the presence of** ***H. pylori*** **antigen using rapid test strip. Besides, standard volume of blood sample were also collected and analyzed using BD FACS count and Sysmex K-21, in order to estimate CD4+ T cell count and white blood cell count. A P-value <0.05 was considered as statistical significant. The prevalence of** ***H. pylori*** **infection among TB patients and non TB controls were 48 (40%) and 15 (12.5%), respectively. Alcoholic individual (AOR = 7.2 (95% CI: 1.97-26.2) and 6.2 (95% CI: 1.6-24.71,) were significantly associated with the development of** ***H. pylori*** **infection in TB cases and healthy controls respectively, underweight (AOR= 4.1 (95% CI: 1.46-11.53) and lymphocyte count <20% (AOR=11.3 (95% CI: 1.6-45) were significantly associated with the development of** ***H. pylori*** **infection in TB cases.** ***H. pylori*** **infection among TB patients was significantly higher than non TB controls. Health education targeting on the risks of** ***H. pylori*** **infection should be considered to the general population.**

KEYWORDS: ***Prevalence, H. pylori,*** **active Tuberculosis, CD4+ Lymphocyte.**

INTRODUCTION

Helicobacter pylori (*H. pylori*) is a slow growing, microaerophilic, gram negative bacterium, whose most striking biochemical characteristics are the abundant production of urease, positivity for oxidase, and catalase. This bacterium colonizes gastric mucosa and elicits both inflammatory and lifelong immune responses with release of various bacterial and host-dependent cytotoxic substances [1]. Pathological studies and extensive clinical trials, carried out in the past few years, have proved the causative role of *H. pylori* in the development of chronic gastritis [2] and peptic ulcer disease [3].

The majority of infected people remain asymptomatic, and only small portions develop illness, usually in adulthood. *Helicobacter pylori* cause upper gastrointestinal disease such as gastritis, peptic ulcer disease and also increase the risk of gastric cancer. The prevalence of *H. pylori* closely tied to socioeconomic conditions and accordingly, this infection is more common in developing countries than in developed world [4].

It is known that *H. pylori* infection is strongly associated with various extra gastro- duodenal disorders including cardiovascular, skin, rheumatic, liver and respiratory diseases. Most importantly, there are controversial evidences regarding the relationship between *H. pylori* infection and pulmonary tuberculosis. Evidently, infection with *H. pylori*

was found to be protective against tuberculosis, as it is indicated; *H. pylori* infection up regulates the production of immunological parameter, notably, production of interferon-gamma, and other cellular responses, subsequently leading to infected macrophages to be sequestered within organized lung granulomas [5, 6].

In contrast, other studies claimed that *H. pylori* infection is possibly one of the risk factors for the occurrence of respiratory diseases including tuberculosis [1, 7]. They hypothesized that persistent inflammatory responses related to *H. pylori* infection could provoke many respiratory disorders, such as chronic bronchitis, bronchiectasis, asthma, lung cancer and tuberculosis [8, 9]. Moreover, few study have shown that no significance different in prevalence of *H. pylori* infection among patients with and without tuberculosis [10].

Helicobacter pylori has been recognized as a public health problem worldwide (affecting approximately 50% of the world population and more prevalent in developing than the developed countries, In various regions of sub-Saharan Africa, for example, 61–100% of the population may harbor the pathogen; young children have the highest prevalence [11]. *Helicobacter pylori* infection cause considerable morbidity, and impose a major burden upon health care systems worldwide [12].

Today, *Helicobacter pylori* is recognized as the most common cause of gastritis, which in turn leads to the development of more gastrointestinal complications such as peptic and duodenal ulcers. Additionally, In 1994, an International Agency for Research on Cancer Working Group found sufficient evidence to the organism is classified as a class 1 carcinogen because of its causal relationship to gastric adeno carcinoma, one of the world's deadliest cancers [13, 14].

Tuberculosis is among major public health problems throughout the world and its burden remains to be enormous. Ethiopia is the tenth high-TB burden country in the world, with an estimated of 201,914 new cases of TB (incidence rate 224 per 100,000 populations) reported in 2013 [15].

Both Mycobacterium tuberculosis (*Mtb*) and *Helicobacter pylori* are more common among persons of low socio- economic status and those living in densely populated areas, presumably because they are transmitted person-to-person [16-19].

A History of Pulmonary tuberculosis might be associated with increased prevalence of *H. pylori* infection [20]. To the best of our knowledge, there is no study conducted in this area, about *H. pylori* infection among with and without active pulmonary tuberculosis, hence conducting this study and address this issue may fill the existing gap. So the main objective of this study is to assess the prevalence and associated risk factors of *H. pylori* infection among patients with active pulmonary tuberculosis and healthy controls.

MATERIALS AND METHODS

The study was conducted in selected TB diagnosis and treatment centers of health facilities of North Gondar, North west Ethiopia namely (Gondar University referral hospital, Debark District Hospital, kolladiba HC, sanja HC and HC found in Gondar town). A comparative cross-sectional study was conducted from February to May 2017. All patients with active pulmonary TB infection and apparently healthy control attending at all selected health facilities providing the TB diagnosis and treatment service during the study period were source population. All voluntary individual with active pulmonary tuberculosis infection and apparently healthy control was included in the study. Socio-demographic variables (like; Sex, Age, Educational level, Occupation, Place of residence, family size and nutritional status), HIV status, behavioral risk factors (like; smoking habit and drinking alcohol), CD4 level and hematological parameters (complete blood count).

Convenient sampling technique was used. Before collecting the socio-demographic and factors associated with *H. pylori* infection, informed consent and assent was obtained from adult and children patients respectively. The data was collected by trained data collectors using pre-tested questionnaire with guided interview. Socio-demographic variables like (age, sex, education level, occupation, family size and other relevant data, such as nutritional status, habits of smoking and alcohol drinking were obtained. HIV statuses were obtained from patients' card.

Stool collection and processing

About 3 gm of stool specimen was collected in a clean, dry stool cup from the cases study subject and control study subject, specimens were transported in to the laboratory thereby samples were analyzed. The *H. pylori* test strip was removed from the pouch and the plastic dropper filled with the stool specimen. Holding the dropper vertically and add one drop of specimen into the sample pad. Then add one drop (35 –50 µL) of sample diluents immediately. When an adequate volume of extracted fecal specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action across the cassette. *Helicobacter pylori* antigens if present in the

specimen was bind to the anti- *H. pylori* conjugates [21]. The immune complex is then captured on the membrane by the pre coated antibody, forming a burgundy colored T band, indicating an *H. pylori* positive test result. Absence of the T band suggests that the concentration of *H. pylori* antigens in the specimen is below the detectable level, indicating an *H. pylori* negative test result.

Blood specimen collection and processing

Blood sample was collected strictly following standard operational procedures, disinfecting the phlebotomy site by swabbing the skin in small outward circles with 70% alcohol swab or cotton wool soaked in isopropyl alcohol from each study participants. Five ml of venous blood was drawn in the EDTA vacationer tube; mix the blood properly by inverting the tube 6-8 times to avoid formation of small clots. The blood sample was stored at room temperature, arrange for immediate transport of the sample to testing laboratory sites to perform CD4 counts and other hematological tests for determination of hematological parameters (Complete Blood cell Count).

Prior to running patient specimens, Calibration of FACS count flow cytometry and quality control was done by known value samples according to the instruments manual for both the reagent and the machine. The specimens are analyzed on a Sysmex K-21 and a flow cytometry machine to determine the Complete blood counting and proportion of cells of a particular phenotype respectively [22].

Quality control

The reliability of the study findings was guaranteed by implementing Quality control (QC) measures throughout the whole process of the laboratory work. SOPs were strictly followed and internal quality controls materials included from the test kits were performed based on manufacturer instructions. Before data collection the comprehensiveness, reliability and validity of questionnaires was pre tested on ten pulmonary Tuberculosis patients of Metma Hospital.

Data entry and analysis was accomplished by using SPSS version 20 computer software. The result was presented through tables and charts. The associations between independent variables and *H. pylori* infection, or *H. pylori* infection among groups were examined by using univariate and multivariable logistic regressions. Odds ratio and 95% confidence interval will be used to measure the strength of an association. P-value of <0.05 will be considered a statistically significant

The study was approved by the Ethical review committee of the Department of Medical Microbiology, School of Biomedical and Laboratory Sciences, University of Gondar. Ethical review committee and official letter of co-operations was provided to Gondar referral hospital, Debark district hospital and health centers prior to data collection. Study participants also informed that all data and sample obtained from them was kept confidential by using codes instead of any personal identifiers and is used only for the purpose of the study.

RESULTS

Socio-demographic characteristics

A total of 240 (120 TB Patients and 120 non-TB controls) study participants were included in this study. The majority of the participants were males, 143 (59.6%) and 171(71.3) was in the age group of 18- 34 years. The mean age was 30.41 (±11.09) ranged from 12-80 years. More than half of the study participants (53.8%) reported that they lived with more than three people in the same house. Most of the study participants were college and above 103(42.9) and urban residents 171 (71.2). Nearly 88% and 76% of the study participants were non cigarette smokers and non-alcohol users, respectively (Table 1).

Prevalence of *H. pylori* infection

From the total of 240 study participants, the overall prevalence of *H. pylori* infection was 26.3 %(63). Prevalence of *H. pylori* infection among TB patients and non-TB controls study Participants were 40 % (48/120) and 12.5% (15/120) respectively. The prevalence of *H. pylori* infection was among TB patients significantly higher (COR=4.67, 95% CI: 2.43-8.96, P=<0.001*) in TB patients 48/120 (40%) than non TB controls 15 /120 (12.5) (Figure 1). Age specific prevalence for <18 years, 18-34 years, 35-44 years and greater 45 years were 1/48 (2.8%), 24/48 (50%), 9/48 (18.7), 14/48(29.17) respectively.

Among all of the TB patients 4 (3.3 %) were HIV positive and *H. pylori* infection was observed in two of HIV-TB co-infected individuals. On the other hand, among HIV negative individuals 46/116 (39.7%) of them were infected with *H. pylori* infection. Among all non TB controls was HIV negative. There was no difference with prevalence of *H.*

pylori infection among some socio demographic characteristics like place of residence, the number of person per house hold, educational background, and occupational status of the study subjects (Table 2).

Table 1. Socio demographic and Behavioral characteristics of the study participants in North Gondar, North west Ethiopia, from February to May, 2017 (n = 240)

	Characteristics	TB patients n=120	Non TB controls n=120	Total n (%)
Mean (±SD)	Mean (±SD)	32.77 (±13.79)	28.05 (±6.76)	30.41 (±11.09)
Age group (year)	<18	4(3.3)	3(2.5)	7(2.9)
	18-34	69(57.5)	102(85)	171(71.3)
	35-44	21(17.5)	11(9.2)	32(13.3)
	>45	26(21.7)	4(3.3)	30(12.5)
Female		54(45)	43(35.8)	97(40.4)
Educational status	Unable to read and write	47(39.2)	6(5)	53(22)
	Primary	41(34.2)	10(8.3)	51(21.3)
	Secondary	17(14.2)	16(13.3)	33(13.8)
	Collage and above	15(12.4)	88(73.3)	103(42.9)
Occupational status	Governmental employee	9(7.5)	76(63.3)	85(35.4)
	Nongovernmental	15 (12.5)	5(4.2)	20(8.3)
	Farmer	31 (25.8)	4(3.3)	35(14.6)
	Merchant	8(6.7)	7(5.8)	15(6.3)
	House wife	27(22.5)	5(4.2)	32(13.3)
	Student	30(25)	23(19.2	53(22.1)
Place of residence	Rural	52(43.4)	17(14.2)	69(28.8)
	Urban	68(56.6)	103(85.2)	171(71.2)
Family size	<3	25(20.8)	37(30.8)	62(25.8)
	3-5	70(58.3)	59(49.2)	129(53.8)
	>5	25(20.8)	24(20)	49(20.4)
Habit of alcohol drinking	Alcoholic	29(24.2)	25(20.8)	54(22.5)
	Non-alcoholic	91(75.8)	95(79.2)	186(77.5)
Habit of smoking cigarette	Smoker	15(12.5)	1(0.8)	16(6.7)
	Non smoker	105(87.5)	119(99.2)	224(93.3)
HIV sero status	Negative	116(96.7)	120(100%)	236(98.3)
	Positive	4(3.3)	0(0%)	4(1.7)
BMI (kg/m2)	Mean (±SD)	18.5(±2.13)	21.41(±2.17)	20.03(±2.23)
	<18.5	60(50%)	8(6.7)	68(28.3)
	18.5-24.9	60(50%)	107(89.1)	167(69.6)
	25-29.9	(0.0%)	5(4.2)	5(2.1)

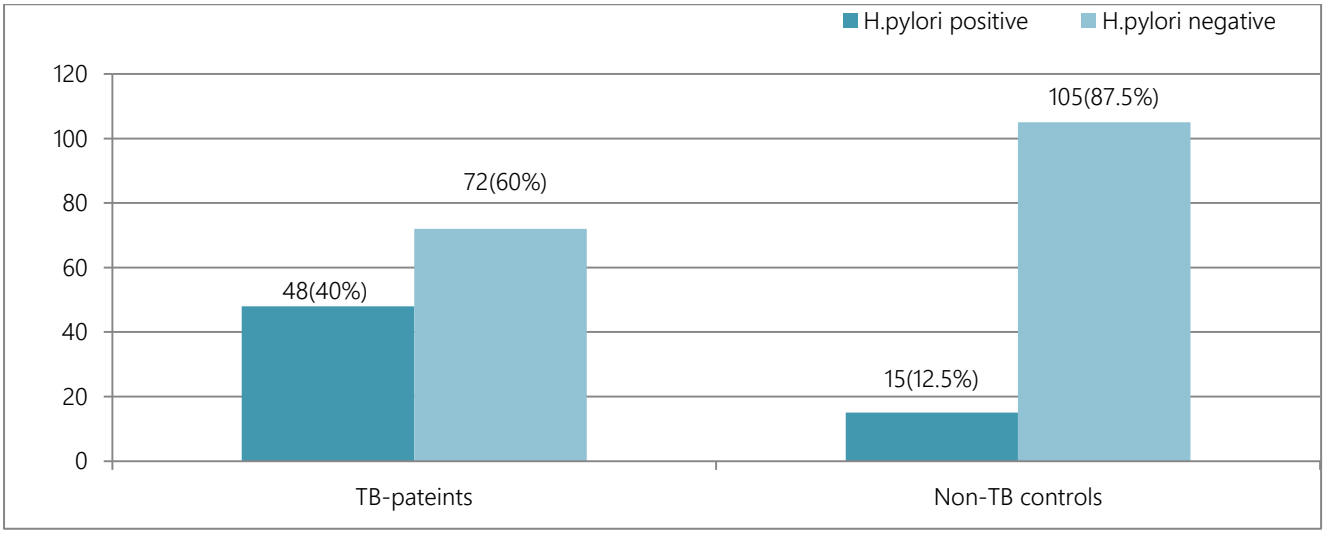

Figure 1. Prevalence of *H. pylori among* TB patients and non TB controls in North Gondar, North west Ethiopia, from February to May, 2017.

Table 2. Association between the prevalence of *H. pylori* infection and some of the risk factors among study participant in North Gondar, North west Ethiopia, from February to May, 2017 (n = 240)

	Characteristics	*H. pylori* Status		COR (95%CL)	P- Value	AOR(95%CL)	P-Value
		Positive	Negative				
Sex	Male	36(57.14%)	107(60.45%)	0.87(0.48-7.03)	0.64		
	Female	27(42.86%)	70(39.55%)	1			
Age group (year)	<18	1(1.59%)	6(3.39%)	1			
	18-34	37(58.73%)	134(75.71%)	1.65(0.19-14.2)	0.64		
	35-44	10(15.87%)	22(12.43%)	2.72(0.28-25.7)	0.38		
	>45	15(23.81%)	15(8.47%)	6(0.64-56)	0.21		
Educational status	Unable to read & write	22(34.9%)	31(17.5%)	3.85(1.79-8.27)	0.001*	0.51(0.07-3.53)	0.5
	Primary	19(30.2%)	32(18.1%)	3.22(1.48-7.03	0.003*	1.33(0.28-6.19)	0.71
	Secondary	6(9.5%)	27(15.3%)	1.20(0.43-3.39)	0.70	0.63(0.12-3.09)	
	Collage and above	15(12.4)		1			
Occupational status	Governmental	11(17.5%)	74(41.8%)	1		1	
	Nongovernmental	6(9.5%)	14(7.9%)	0.56(0.22-1.42	0.22		
	Farmer	16(25.4%)	19(10.7%)	1.63(0.51-5.24)	0.40		
	Merchant	6(9.5%)	9(5.1%)	3.21(1.25-8.22)	0.15*	4.35(0.73-25)	0.1
	House wife	13(20.6%)	19(10.7%)	2.54(0.74-8.69)	0.13*	6.32(0.99-4)	0.06
	Student	11(17.5%)	42(23.7%)	2.61(0.99-6.88)	0.52		
Place of residence	Rural	23(36.5%)	46(26%)	1.63(0.88-3.02)	0.11*	0.31(0.08- .19)	0.09
	Urban	40(63.5%)	131(74%)			1	
Family size	<3	15(23.8%)	47(26.6%)	1			
	3-5	36(57%)	93(52.5%)	0.98(0.41-2.35)	0.97		
	>5	12(19%)	37(20.9%)	1.19(0.56-2.5)	0.64		
Habit of alcohol	Alcoholic	29(46%)	25(14.1%)	5.18(2.70-9.94)	<0.001*	6.2(2.3-16.12)	<0.001*
	Non-alcoholic	34(54%)	152(85.9%)	1		1	
Habit of smoking	Smoker	13(20.6%)	3(1.7%)	15(4.13-55)	0.001*	11.7(1.9-70)	0.007
	Non smoker	50(70.4%)	174(98.3%)	1		1	
HIV status	Negative	61(96.8%)	175(98.9%)	1			
	Positive	2(3.2%)	2(1.1%)	0.34(0.04-2.52)	0.29		
BMI (kg/m2)	<18.5	35(55.6%)	33(18.6%)	--	0.99		
	18.5-24.9	28(44.4%)	139(78.5%)	--	0.99		
	25-29.9	0(0.0%)	5(2.8%)	1			
CD4 count	200 cells/mm3	31(49.2%)	18(10.2%)	2.8(6.08	<0.001*	1.9(3.06	0.002
	200-500 cells/mm3	30(47.6%)	126(71.2%)	0.3(0.84	0.07*	2.2(0.41	0.34
	>500 cells/mm3	2(3.2%)	33(18.6%)	1	1		
Lymphocyte count %	>20%	23(36.5%)	7(4%)	14(5.09-10.7)	0.001*	6.1(1.36-27.2)	0.01
	20-40%	27(43%)	113(63.8%)	1.04(0.50-2.18)	0.90		
	>40%	13(20.5%)	57(32.2%)	1			
TB status	Yes	48(76.2%)	72(40.7%)	4.66(2.43-8.96)	<0.001*	1.32(0.41-4.27)	0.63
	No	15(23.8%)	105(59.3%)	1		1	

Association between risk factors with *H. pylori* Infection among TB patients and non TB controls

There was no statistically significance association between *H. pylori* infection and socio demographic characteristics of the study participants including gender (COR=0.87, 95% CI 0.48-7.03, P =0.64), place of residence (COR=0.89, 95% CI (0.42-1.87, P= 0.76) and house hold crowding (AOR=0.28, 95% CI (0.05-1.39, P=0.52) (Table 2). However, significant higher prevalence of *H. pylori i*nfection was observed among TB patients with lymphocyte count less than 20%, 21/48 (43.8%) than with lymphocyte count 20-40% and greater or equal to 40% , TB patients who had lymphocyte count of less than 20% were almost eleven times more likely to be infected by *H. pylori* than TB patients who had lymphocyte percentage count of 20-40% and greater than or equal to 40% (AOR=11.3, 95% CI=2.8-45, P=0.001) (Table 3).

TB positive individuals and apparently healthy controls who had habit of drinking alcohol were seven and sex times more likely to be affected by *H. pylori* infection as compared to individuals who don't had habit of drinking alcohol (AOR=7.2, 95% CI (1.97-26.25); P=0.003 and AOR=6.2, 95% CI: (1.6-24.7), respectively (Table 4).

There was an association between *H. pylori* infection and smoking cigarettes (AOR=18.3, 95CI (2.2-151) P=0.007. While, significant higher prevalence of *H. pylori* infection was observed among TB patients with underweight (<18.5 kg/m^2) 33/48 than with (68.8) BMI value with normal range ,greater or equal to 18.5 kg/m^2 - 24.5 kg/m^2, 15/48(31.2%). TB patients who had BMI value less than 18.5 kg/m^2, were almost four times more likely to be infected by *H. pylori* than TB patients who had BMI value greater than 18.5 kg/m^2 - 24.5 kg/m^2 (AOR =4.11 95% CI: 1.46-11.53, P= 0.007 (Figure 2).

Higher prevalence of *H. pylori* infection was observed among TB patients with CD4+lymphocyte count less than 200 cells/mm^3 23/48 (58.3%) than with CD4 + lymphocyte count of greater or equal to 500 cells/mm^3 but There was no statistically significance association (COR= 4.4,95 CI: 0.6-28, P=(0.92) (Figure 3).

Table 3. Multivariate association of socio demographic characteristics and risk factors to the prevalence of *H. pylori* infection among TB positive individuals, in North Gondar, Northwest Ethiopia, 2017

H. pylori infection Variables	Negative n (%)	Positive n (%)	COR (95% CI)	P-value	AOR (95%CI)	P-value
Alcohol drinking habit						
Alcoholic	7(24.1)	22(75.9)	7.86(3.0-20.6)	<0.001*	7.2(1.97-26.25)	0.003*
Non-alcoholic	65(71.4)	26(28.6)	1			
Family size						
<3	13(52)12(48)	1				
3-5	41(58.6)29(41.4)	0.77(0.31-1.9)	(0.57)	0.52(0.15-1.80)	0.30	
>5	18(72)7(28)	0.42(0.13-1.36)	(0.15)	0.28(0.05-1.39)	0.52	
Smoking habit						
Smoker	2(13.3)	13(86.7)	13(2.7-60)	(0.001)*	11.1(1.5-81)	0.007*
Non-smoker	70(66.7)	35(33.3)	1			
BMI range						
<18.5	27(45.8)	32(54.2)	3.3(1.6-7.9)	(0.02)*	4.1(1.46-11.53)	0.007*
18.5-24.5	45(73.8)	16(26.2)	1			
Lymphocyte % range						
<20%	7(25)	21(75)	8(2.1-29)	(0.002)*	11.3(2.8-45)	0.001*
20-40%	50(68.5)	23(31.5)	1.5(0.5-4.7)	(0.45)		
>40%	15(78.9)	4(21.1)	1			

*Statistically significant.

Table 4. Multivariate association of socio demographic characteristics and risk factors to the prevalence of *H. pylori* infection among healthy controls in North Gondar, Northwest Ethiopia, 2017

Characteristics	Controls N=120					
	H. pylori status		P-value	COR (95% C.I.)	P-value	AOR (95% C.I.)
	Positive	Negative				
Family size						
<3	3(20%)	34 (32.4%)	1	1	0.40	
3-5	7(46.7%)	52(49.5%)	0.56	1.5(0.37-6.3)	0.14	2.09(0.37-11.7)
>5	5(33.3)	19 (18.1)	0.16	2.9(0.64-13.9)		4.3(0.62-29)
Habit of alcohol drinking						
Alcoholic	7(46.7%)	18(17.1%)	0.01	4.2(1.36-13)	0.009	6.2(1.6-24.7)
Non-alcoholic	8(53.7%)	87(82.9%)	_	1.00	_	1
CD4 count						
<200cells/mm3	3(20%)	6(5.7%)	0.07	6.5(0.88-47)	0.34	3.8(0.24-61%)
200-500 cells/mm3	10(66.7%)	73(69.5%)	0.47	1.7(0.36-8.6)	0.39	2.1(0.39-11.8%
>500cells/mm3	2(13.3%)	26(24.8%)	1	1		
Lymphocyte count%						-
<20%	2(13.3%)	0(0%)	0.99	0.29(0.08-1.02)	0.99	0.22(0.56-0.89)
20-40%	4(26.7%)	63(60%)	0.05	-	0.34	1
>40	9(60)	42(40%)	1	1		

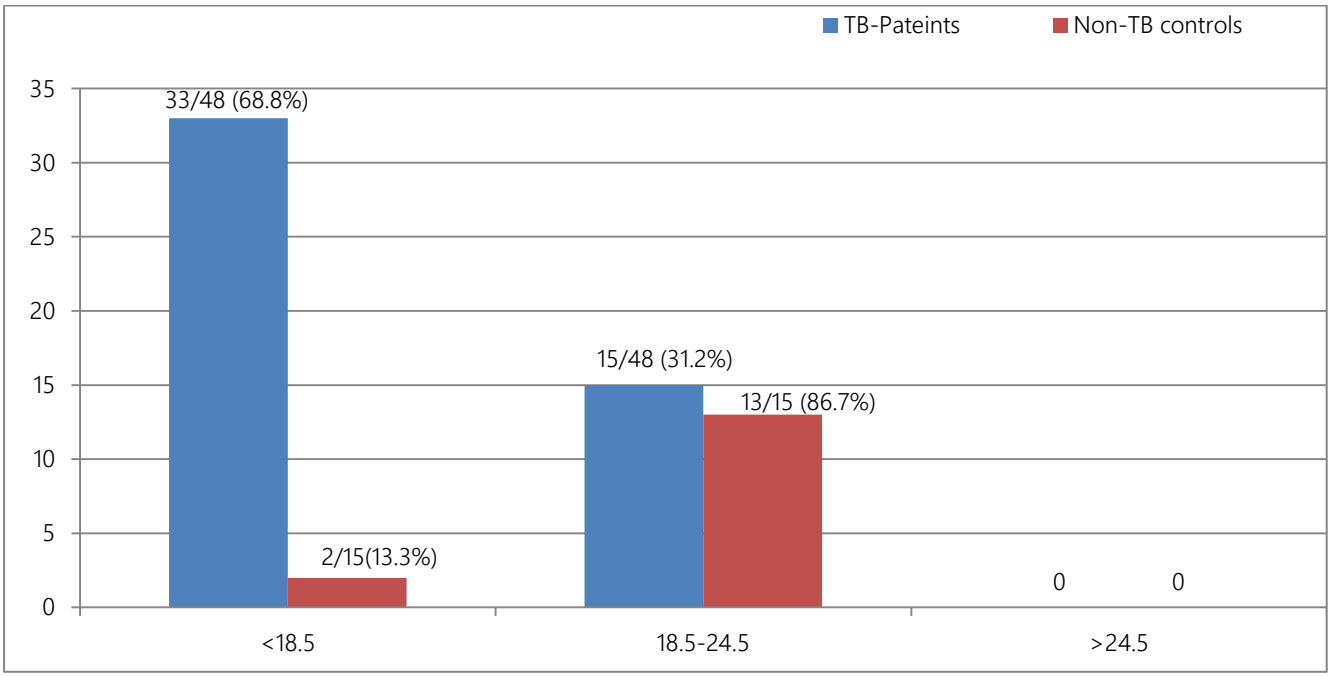

Figure 2. *H. pylori* prevalence among TB patients and non TB controls according to the BMI value.

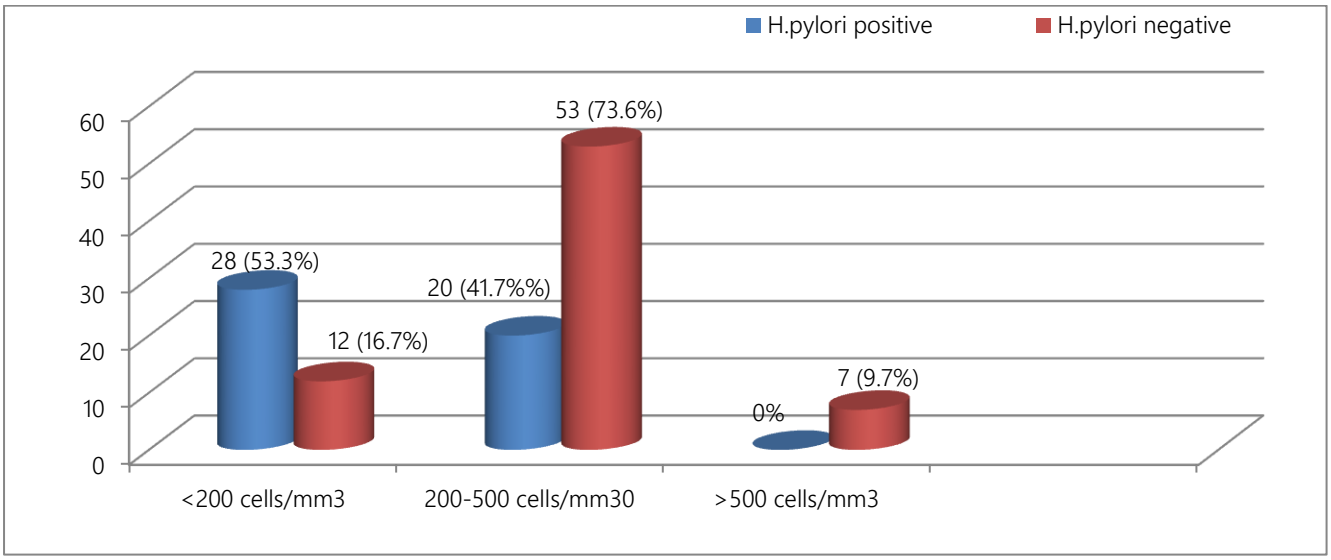

Figure 3. Distribution of *H. pylori* positive and negative in patients with TB according to CD4 count level.

DISCUSSION

H. pylori is the main cause of chronic stomach inflammation, peptic ulcer, duodenal ulcer, non-ulcerous dyspepsia, gastric cancer, and gastric mucosa associated lymphoid tissue (MALT) lymphoma [23]. To the best of our knowledge, information concerning prevalence of *Helicobacter pylori* among Active pulmonary tuberculosis and healthy controls in particular is not available in Ethiopia. In this study we found, an overall prevalence of 26.3 % (63/240). However, there is report from Canada (in Ontario) with lower prevalence of *H. pylori* infection 23.1 %. The low prevalence in this study may be attributed to differences in study area, subjects, and socio demographic characteristics [24].

This study aimed to see if any difference was found Active pulmonary tuberculosis and healthy controls. Prevalence among active pulmonary tuberculosis (40%, 48/120) is higher than non-TB controls (12.5 %, 15/120). Thus, it is indicated that TB patients and TB negative individuals have different susceptibility for the colonization *H. pylori* in gut, This finding is similar with study conducted in Jmma by Kebede et al. [25], that reported the

prevalence of *H. pylori* infection was 19/54 (35.2%) and 11/54 (20.4%) in TB infected patients and non TB controls, respectively. However, the laboratory method is different as they used ELISA for Stool Antigen Detections [25].

Other studies conducted on the same type of study participants with the present study, showed different findings than the present study. For example, a study conducted in Athens reported *H. pylori* infection with prevalence of 87.5% and 61.4% among TB infected patients and control groups, respectively which is higher than the present study. The difference might be due to difference in socio demography, and especially the laboratory methods is quite different [26].

Prevalence of *H. pylori* in respect of gender did not show statistically significant associations with this study even though males were with higher prevalence (COR=1.09, 95%CI: 0.52-2.27, P=0.82). However, this was agreed with the findings reported from Jimma which showed that there was no a significant association [25].

When we see Prevalence of *H. pylori* in respect of drinking habit of alcohol show statistically significant associations with this study (AOR=7.2, 95%CI: 1.97-26.25, P= 0.003). This finding was agreed with the findings reported by Moges et al. [37] in Gondar. This showed that there was a significant association [27]. Prevalence of *H.pylori* in respect of habit of smoking cigarette also shows statistically significant associations with this study (AOR=18.3, 95%CI: 2.2-151, P= 0.007). This was agreement with the findings reported from Turkey which showed that there was a significant association [28].

Prevalence of *H. pylori* in respect of CD4 + lymphocyte count less than 200 cells/mm^3 not show statistically significant associations with this study even though CD4 + count less than 200 cells/mm^3 were with higher prevalence (COR=4.4, 95%CI 0.6-28, P=0.92). However, this was not in agreement with the findings reported from jimma which showed that there was a significant association [25]. This difference might be due to decrease HIV positivity of study participant in this study.

TB diseases might be associated with increased prevalence of *H. pylori* infection. To date, different studies on association between *H. pylori* infection and respiratory disease have been investigated. However, these studies concluded differently. For example study from Peruvian has reported that there is no association with *H. pylori* and TB disease [7]. Other hand, study among Gambian and Pakistan reported being *H. pylori* infected may contribute to being less to develop active TB disease [29, 30]. However, in the present study the prevalence of *H. pylori* infection was higher among TB patients than non TB controls.

Other variables such as Age, occupational status, place of residence and the number of person per household were not statistically associated with *H. pylori* in this study. This result was not comparable with the study done in South Africa and Gondar [27, 31]. The difference may be due to the difference in sample size, study settings and design.

The cross sectional nature of this study has a limitation to show cause and effect associations between *H. pylori* infections with some associated risk factors like habit of alcohol, habit of smoking cigarette, needs to be investigated in cohort type of studies and the determination of H. pylori infection was with only one method by (*H. pylori* stool antigen test kit); even though the HpSA kit employed in this study have Sensitivity 98.8%, specificity 100% and Accuracy 98.9 %. (user leaflet of kits)

CONCLUSIONS AND RECOMMENDATIONS

In conclusion, the present study showed that patients with pulmonary TB have an increased prevalence of *H. pylori* infection the data compare with apparently health controls in the same study area. The overall prevalence of *H. pylori* infection in TB positive patients and healthy controls was 48 (40%) and 15 (12.5%), respectively. Factors like level of lymphocyte count %, body mass index, smoking habit of cigarette and drinking habit of alcohol were significantly associated with *H. pylori* infection. Socio demographic characteristics like gender, age occupational status and place of residence showed statistically no significant Association with *H. pylori* infection in this study.

Recommendation

- Health education targeting on the risks of *H. pylori* infection should be considered to the general population.
- Our results must be confirmed in a larger number of patients and different laboratory methods.
- Further studies are required in the community using different diagnostic methods to explore the actual role of *H. pylori* in and we recommend that a large scale study to be conducted to further elucidate the role of *H. pylori* infection and warranted to consider weather screening *H. pylori* infection for benefit of pulmonary tuberculosis patients.
- Generally, a cohort study will reveal details of the dynamics of *H. pylori* infection in the studied population

DECLARATIONS

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Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

Authors' Contribution

Debaka Belete participated in the conception, design, acquisition of the data and statistical analysis interpretation of the data, drafting of the paper, and critical revision of the manuscript. Setegn Eshete, and Birhanemeske Tegene participated in the design and critical revision of the manuscript. All authors read and approved the final manuscript.

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Competing interests

All authors declare that they have no Competing interest.

Ethical approval

We would like to confirm that the study protocol was thoroughly reviewed and approved by the University of Gondar College of Health Sciences, School of Biomedical and Laboratory Sciences Research Ethics committee (REC). A permission letter was obtained and sent to all concerned bodies, and the study was secured at all levels. Furthermore, the Research Ethics Committee (REC) has waived the need for consent due to the retrospective study and the utilization of secondary and anonymized data. We conducted the study following the Declaration of Helsinki [32].

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