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"BURDEN OF ANTITUBERCULAR DRUG-INDUCED HEPATOTOXICITY AMONG TUBERCULOSIS AND OTHER RESPIRATORY TRACT INFECTED PATIENTS ADMITTED TO A QUATERNARY CARE HOSPITAL, BELAGAVI."

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ABSTRACT

Background

Most common adverse effect causing cessation of anti-tubercular treatment is drug-induced liver injury which is unpredictable due to its idiosyncratic nature. ATT is the most common cause of DILI and drug-induced acute liver failure in South East Asia.

Material and Methods: A case control study conducted on 'Burden of antitubercular drug-induced hepatotoxicity among tuberculosis and other respiratory tract infected patients admitted to a quaternary care hospital, Belagavi'. Aim of the study is to evaluate the burden of antitubercular drug-induced hepatotoxicity among tuberculosis patients constituting the case group with demographic variables.To examine the distribution of respiratory tract infection patients without hepatotoxicity serving as the control group with demographic variables.To evaluate the relationship between antitubercular drug-induced hepatotoxicity cases and the control group with demographic variables.Researcher employed descriptive research approach with purposive sampling method, total population the study were 160.

Results: There will be a strong positive linear relationship between tuberculosis patients with adverse drug reactions (Case Group) and respiratory tract infection patients without adverse drug reactions (Control Group). Regression analysis will be 0.9, P-value is > 0.05 level of significance, and table value is 1.943.

Conclusion: At the conclusion of the study, a significant association was found between case group and control group with selected demographic variables. Additionally, Karl Pearson's correlation coefficient indicated a strong positive relationship between the two.

KEYWORDS: Antitubercular drugs, hepatotoxicity, tuberculosis, respiratory tract infections, and quaternary hospital.

INTRODUCTION

Drug-induced liver injuryis a liver disorder caused by medications that damage hepatocytes and other liver cells, resulting in impaired liver function after excluding other possible causes. DILI is a significant contributor to acute liver failure and is associated with considerable morbidity and mortality. It is also one of the major adverse effects responsible for the discontinuation of clinical drug development programs and the withdrawal of medications from the market. Among the various causative agents, antimicrobial drugs are the most common contributors to drug-induced acute liver failure, with first-line anti-tuberculosis (anti-TB) medications being recognized as a leading cause worldwide.[1]

Tuberculosis is a contagious disease that can be effectively cured through the use of combination antitubercular therapy. Standard treatment regimens, which include isoniazid, rifampicin, pyrazinamide, ethambutol, and streptomycin, have demonstrated significant success in managing the disease. However, these medications are often associated with adverse drug reactions, which may compromise treatment adherence and potentially result in therapeutic failure.[2]

Despite the widespread use of anti-tuberculosis medications and the large number of patients treated globally over several decades, the exact mechanisms responsible for drug-induced hepatotoxicity remain inadequately understood. Research focused on identifying drug-related factors, genetic predispositions, and environmental influences associated with susceptibility to hepatotoxicity, as well as studies exploring the underlying mechanisms of drug-induced liver injury (DILI), may help healthcare professionals develop effective strategies to prevent hepatotoxicity and minimize its adverse outcomes.[3]

Antitubercular drug-induced liver injuryremains a major challenge in the management of tuberculosis, including cases of tuberculosis lymphadenitis. The incidence of ATDILI varies widely across different populations and settings, with reported rates generally ranging from 2% to 30%. This variation is influenced by factors such as demographic characteristics, underlying health conditions, and geographical differences. Although some studies have

reported lower rates of hepatotoxicity among patients with tuberculous lymphadenitis, the hepatotoxic potential of first-line anti-tuberculosis medications continues to make liver injury a significant clinical concern. Several factors increase the risk of developing ATDILI, including advanced age, female sex, existing liver disease, HIV co-infection, poor nutritional status, alcohol consumption, and genetic variations, particularly those affecting the N-acetyltransferase 2 enzymes involved in isoniazid metabolism.[4]

Tuberculosis (TB) continues to be a major global public health concern and remains one of the foremost causes of mortality from infectious diseases. In 2022, an estimated 10.1 million individuals were affected by TB worldwide. The highest burden of the disease was concentrated in the Southeast Asian and African regions, which together accounted for approximately 68% of all cases globally. India contributed the largest share, representing nearly 28% of the global TB burden, with around 2.2 million reported cases and a case-fatality rate of 12% in 2022. The cornerstone of TB management relies on first-line antitubercular drugs, including rifampicin, isoniazid, ethambutol, and pyrazinamide. Although these medications are generally effective and well tolerated, their use may be associated with several adverse effects such as hepatotoxicity, skin reactions, pruritus, joint pain, optic neuropathy, and elevated uric acid levels.[5]

NEED FOR THE STUDY

Tuberculosis (TB) remains a major public health challenge worldwide. Successful treatment requires prolonged administration of anti-tuberculosis medications, typically for duration of six months. Adherence to the prescribed regimen is essential to achieve cure and prevent disease progression; however, adverse drug reactions can negatively impact treatment compliance. Among these reactions, anti-tubercular drug-induced hepatotoxicity is one of the most significant complications, potentially affecting treatment success and patient outcomes. Therefore, assessing the occurrence of anti-tubercular drug-induced liver injury and identifying its associated risk factors among newly diagnosed TB patients is of considerable clinical importance.[6]

The liver's vital function in drug metabolism and detoxification makes it vulnerable to injury. Drug-induced liver damage can be caused by the primary drug's direct toxicity, immune-mediated responses, or metabolites. One typical side effect of first-line anti-TB drugs is hepatotoxicity. The current first-line medications for treating tuberculosis are isoniazid, pyrazinamide, ethambutol, streptomycin, and rifampicin. Cytochrome P-450 is the most important family of liver enzymes involved in the metabolism of anti-tuberculosis

medications. HBV carriers are more susceptible to hepatotoxicity from first-line anti-tuberculosis drugs due to the possibility of HBV reactivation, increased immune system function from TB infection control, decreased metabolism of first-line anti-TB drugs, and pro-inflammatory conditions caused by HBV replication. Symptoms of liver damage often include nausea, vomiting, jaundice, and pain in the abdomen.[7]

OBJECTIVES

- To evaluate the burden of antitubercular drug-induced hepatotoxicity among tuberculosis patients constituting the case group with demographic variables.
- To examine the distribution of respiratory tract infection patients without hepatotoxicity serving as the control group with demographic variables..
- To evaluate the relationship between antitubercular drug-induced hepatotoxicity cases and the control groupwith demographic variables.

HYPOTHESIS

H_1: There is a significant association betweenantitubercular drug-induced hepatotoxicity among tuberculosis patients with demographic variables.

H_2: There is a significant association between respiratory tract infection patients without hepatotoxicity with demographic variables

H_3: There will be strong positive linear relationship betweenantitubercular drug-induced hepatotoxicity and respiratory tract infection patients without hepatotoxicity with demographic variables

RESULTS

Table 1: Distributionof respondents according to their sociodemographic variables.

N=160

Variables	TB with ADR (Case group)	Percentage (%)	RTI without ADR (Control group)	Percentage (%)	Chi-square
Age					
< 40 years	20	25	18	22.5	X^2= 1.41 DF= 16 **P value= 0.9***
40-50 years	18	22.5	23	28.7	
51-60 Years	23	28.7	20	25	
61-70 years	10	12.5	12	15	
>70 years	9	11.2	7	8.7	
Total	**80**	**100%**	**80**	**100%**	
Gender					

Male	45	56.2	47	58.7	X^2= 2.05 DF= 2 P value= 0.01
Female	35	43.7	33	41.2	
Total	**80**	**100%**	**80**	**100%**	
BMI status					
Underweight (<18.5 kg/m^2)	43	53.7	17	21.2	X^2= 1.27
Normal (18.5-25 kg/m^2)	21	26.2	41	51.2	DF= 4
Overweight (>25 kg/m^2)	16	20	22	27.5	**P value= 0.8***
Total	**80**	**100%**	**80**	**100%**	
Cavitation on chest X-ray					
Sputum smear positive (AFB)	80	100	0	0	X^2= 3.06 DF= 1 **P value= 0.8***
Sputum smear negative (AFB)	0	0	80	100	
Total	**80**	**100%**	**80**	**100%**	
Sputum positive molecular test	80	100	0	0	X^2= 3.06 DF= 1 **P value= 0.8***
Sputum negative molecular test	0	0	80	100	
Total	**80**	**100%**	**80**	**100%**	

***p value is > 0.05 level of significance.**

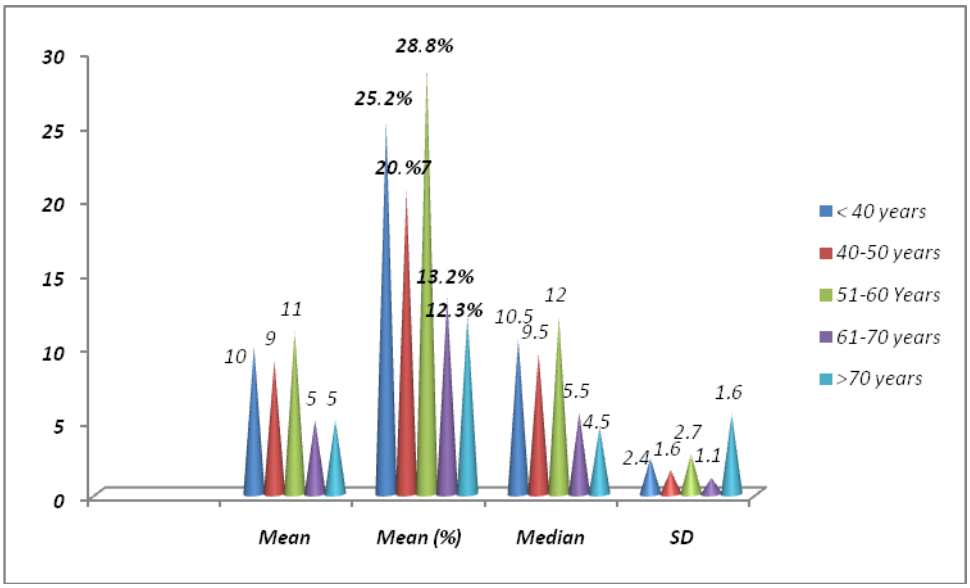
Table 1, revealed thatX^2value calculated among demographic variables such as age, BMI status, cavitation on chest x-ray, were significant at 0.05 levels. Hence it can be interfered that there is a significant association between frequency of respondents according to their demographic variables.

Table 2: Distribution of respondents with their mean, mean percentage, mode, and SD. N=80.

Variables	TB with ADR (Case group)	Mean	Mean (%)	Median	SD
Age					
< 40 years	20	10	25.2	10.5	2.4
40-50 years	18	9	20.5	9.5	1.6
51-60 Years	23	11	28.8	12	2.7
61-70 years	10	5	13.2	5.5	1.1
>70 years	9	5	12.3	4.5	1.6
Total	**80**	**40**	**100%**		
Gender					
Male	45	22.5	56.2	23	1.19
Female	35	17.5	43.7	18	1.6
Total	**80**	**40**	**100%**		

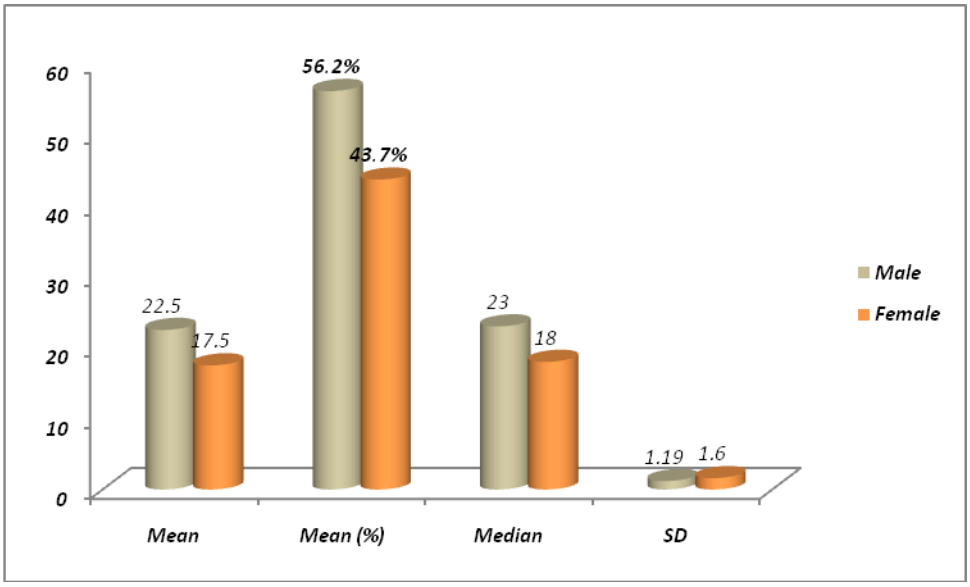
BMI status					
Underweight (<18.5 kg/m^2)	43	21.5	53.7	22	3.7
Normal (18.5-25 kg/m^2)	21	10.5	26.2	11.5	1.4
Overweight (>25 kg/m^2)	16	8	20	10	1.9
Total	**80**	**40**	**100%**		
Cavitation on chest X-ray					
Sputum smear positive (AFB)	80	40	100	20.5	4.3
Sputum smear negative (AFB)	0	0	0	0	0
Total	**80**	**40**	**100%**		
Sputum positive molecular test	80	40	100	20.5	4.5
Sputum negative molecular test	0	0	0	0	
Total	**80**	**40**	**100%**		

***P Value > 0.05 level of significance.**



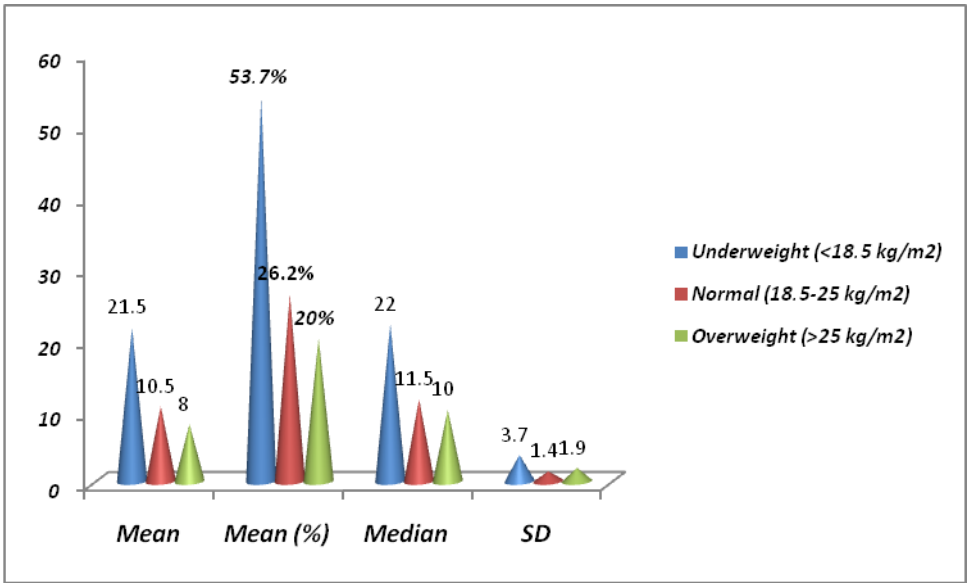
Graph 1: Age distribution with their mean, mean percentage, median, and SD.

Graph 1, revealed that majority of the finding belonged to 51-60 years, of their mean is 11, mean percentage 28.8%, median is 12, and SD + 2.7. More or less similar findings belonged to < 40 years of their mean is 10,mean percentage 25.2%, median is 10.5, and SD+ 2.4. More or less similar findings belonged to 40-45 years of their mean is 9, mean percentage 20.5%, median is 9.5, and SD + 1.6. Less similar findings belonged to 61-70 years of their mean is 5, mean percentage is 13.2, median is 5.5, and SD + 1.1. Less similar findings belonged to > 70 years of their mean is 5, mean percentage 12.3%, median is 4.5, and SD + 1.6.



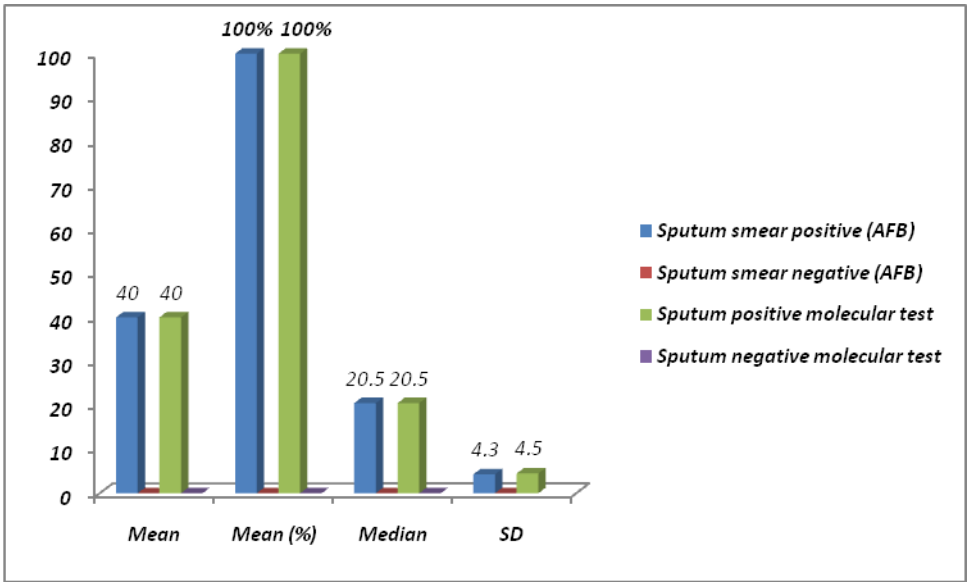
Graph 2: Gender distribution with their mean, mean percentage, median, and SD.

Graph 2, revealed that, majority of the findings belonged to males of their mean is 22.5, mean percentage is 56.2%, median is 23, and SD + 1.19. Less similar findings belonged to females of their mean is 17.5, mean percentage is 43.7%, median is 18, and SD will be 1.6.



Graph 3: BMI status distribution with their mean, mean percentage, median, and SD.

Graph 3, revealed that majority of the findings belonged to underweight of their mean is 21.5, mean percentage is 53.7%, median is 22, and SD + 3.7. More or less similar respondents belonged to normal of their mean is 10.5, mean percentage is 26.2%, median is 11.5, and SD + 1.4. Less similar findings belonged to overweight of their mean is 8, mean percentage is 20%, median is 10, and SD + 1.9.



Graph 4: Distribution of cavitation on chest x-ray with their mean, mean percentage, median, and SD.

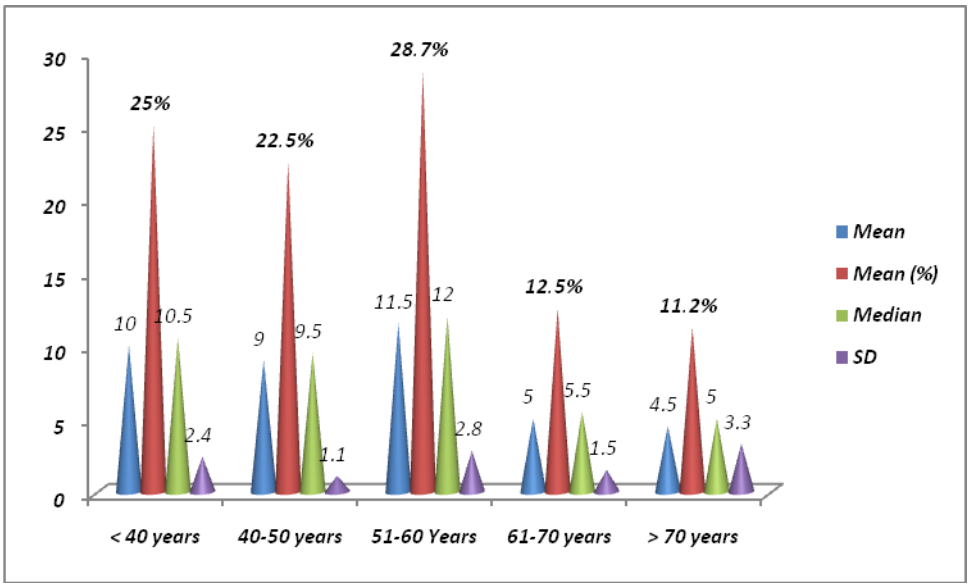
Graph 4, revealed that, majority of the findings belonged to sputum smear positive (AFB) of their mean 40, mean percentage is 100%, median is 20.5, and SD + 4.3. None of the findings belonged to sputum smear negative (AFB). Majority of the finding belonged to sputum positive molecular test of their mean is 40, mean percentage is 100%, median is 20.5, and SD + 4.5. None of the findings belonged to sputum negative molecular test.

Table 3: To evaluate the relationship between antitubercular drug-induced hepatotoxicity cases and the control group with demographic variables (Control group). N=80.

Variables	RTI without ADR (Control group)	Mean	Mean (%)	Median	SD
Age					
< 40 years	25.2	10	25	10.5	2.4
40-50 years	20.5	9	22.5	9.5	1.1
51-60 Years	28.8	11.5	28.7	12	2.8
61-70 years	13.2	5	12.5	5.5	1.5
>70 years	12.3	4.5	11.2	5	3.3
Total	**80**	**40**	**100%**		
Gender					
Male	47	23.5	58.7	24	1.2
Female	33	16.5	41.2	17	1.1
Total	**80**	**40**	**100%**		
BMI status					
Underweight (<18.5 kg/m^2)	17	8..5	21.2	9	1.1
Normal (18.5-25 kg/m^2)	41	20.5	51.2	21	1.9

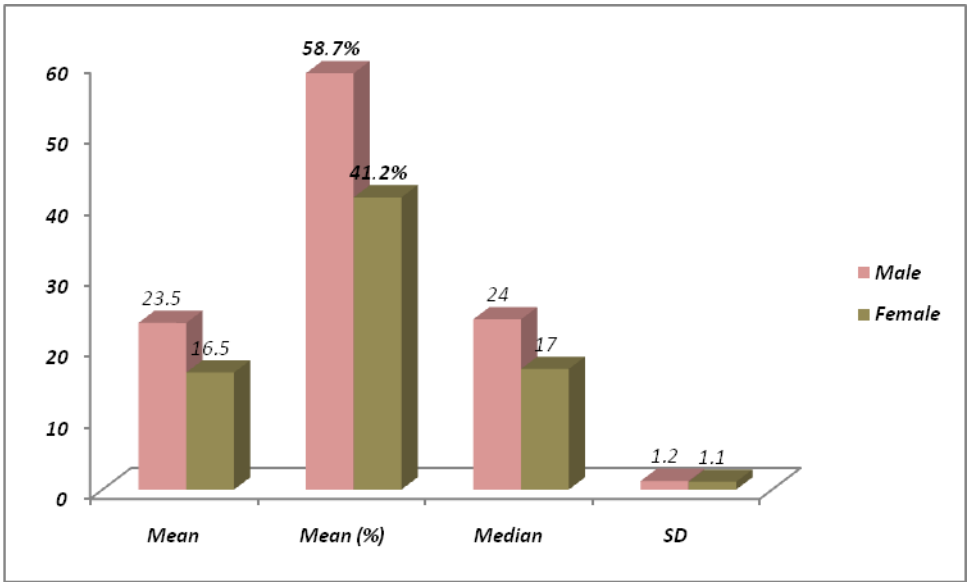
Overweight (>25 kg/m^2)	22	11	27.5	11.5	1.5
Total	**80**	**40**	**100%**		
Cavitation on chest X-ray					
Sputum smear positive (AFB)	0	0	0	0	0
Sputum smear negative (AFB)	100	50	100	49.5	7.7
Total	**100**	**50**	**100%**		
Sputum positive molecular test	0	0	0	0	0
Sputum negative molecular test	100	50	100	49.5	7.7
Total	**100**	**50**	**100%**		

***P Value > 0.05 level of significance.**



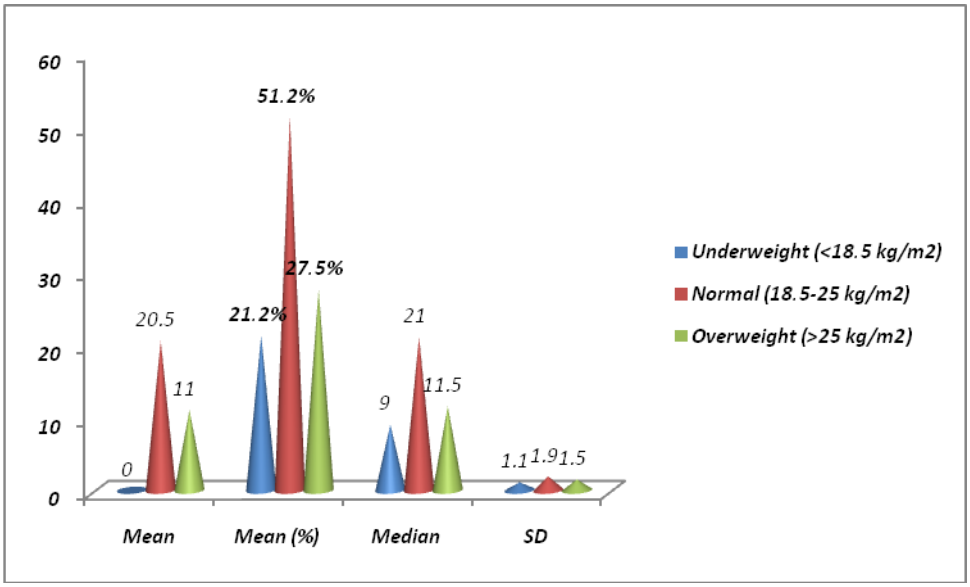
Graph 5: Age distribution with their mean, mean percentage, median, and SD.

Graph 5, revealed that majority of the findings belonged to 51-60 years of their mean is 11.5, mean percentage 28.7%, median is 12, and SD + 2.8. More or less similar findings belonged to < 40 years of their mean is 10, mean percentage 25%, median is 10.5, and SD + 2.4. More or less similar findings belonged to 40-50 years of their mean is 9, mean percentage 22.5%, median is 9.5, and SD + 1.1. More or less similar findings belonged to 61-70 years of their mean is 5, mean percentage 12.5%, median is 5.5, and SD + 1.5. Less similar findings belonged to > 70 years of their mean is 4.5, mean percentage 11.2%, median is 5, and SD + 3.3.



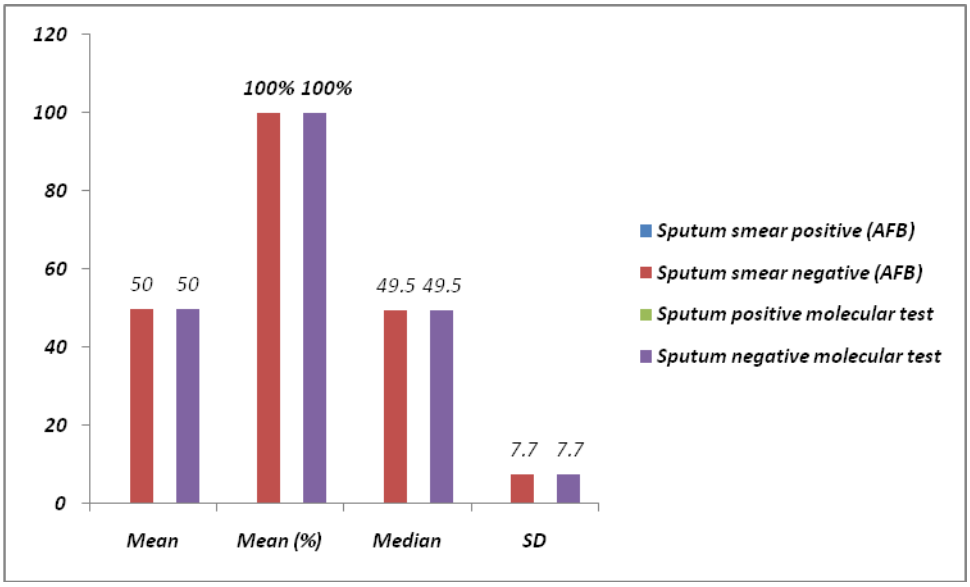
Graph 6: Gender distribution with their mean, mean percentage, median, and SD.

Graph 6, revealed that, majority of the findings belonged to males of their mean is 23.5, mean percentage 58.7%, median is 24, and SD + 1.2. Less similar findings belonged to females of their mean is 16.5, mean percentage 41.2%, median is 17, and SD + 1.1.



Graph 7:BMI status distribution with their mean, mean percentage, median, and SD.

Graph 7, revealed that, majority of the findings belonged to normal of their mean is 20.5, mean percentage 51.2%, median is 21, and SD + 1.9. More or less similar findings belonged to overweight of their mean is 1.5, mean percentage 27.5%, median is 11.5, and SD + 1.5. Less similar findings belonged to underweight of their mean is 8.5, mean percentage 21.2%, median is 9, and SD + 1.1.



Graph 8:Distribution of cavitation on chest x-ray with their mean, mean percentage, median, and SD.

Graph 8, revealed that, majority of the findings belonged to sputum smear negative (AFB) of their mean is 50, mean percentage is 100%, median 49.5, and SD + 7.7, none of the findings belonged to sputum smear positive (AFB), and majority of the findings belonged to Sputum negative molecular test of their mean 50, mean percentage 100%, median 49.5, and SD + 7.7.

Table 4: Correlation between tuberculosis patients with adverse drug reactions (Case Group) and respiratory tract infection patients without adverse drug reactions (Control Group).N=160

Variables	**TB with ADR (Case group)**	**RTI without ADR (Control group)**	**Correlation**
Age			r = 0.9
< 40 years	20	25.2	P Value= 0.05*
40-50 years	18	20.5	T value= 1.943
51-60 Years	23	28.8	
61-70 years	10	13.2	
>70 years	9	12.3	
Gender			
Male	45	47	
Female	35	33	
BMI status			
Underweight (<18.5 kg/m^2)	43	17	
Normal (18.5-25 kg/m^2)	21	41	
Overweight (>25 kg/m^2)	16	22	
Cavitation on chest X-ray			
Sputum smear positive (AFB)	80	0	
Sputum smear negative (AFB)	0	100	

Sputum positive molecular test	80	0	
Sputum negative molecular test	0	100	

***P Value > 0.05 level of significance.**

There will be a strong positive linear relationship between tuberculosis patients with adverse drug reactions (Case Group) and respiratory tract infection patients without adverse drug reactions (Control Group). Regression analysis will be 0.9, P-value is > 0.05 level of significance, and table value is 1.943.

DISCUSSION

In the present study tuberculosis patients with adverse drug reactions (Case Group) findings revealed that;

Findings related to age.

Graph 1, revealed that majority of the finding belonged to 51-60 years, of their mean is 11, mean percentage 28.8%, median is 12, and SD + 2.7. More or less similar findings belonged to < 40 years of their mean is 10, mean percentage 25.2%, median is 10.5, and SD + 2.4. More or less similar findings belonged to 40-45 years of their mean is 9, mean percentage 20.5%, median is 9.5, and SD + 1.6. Less similar findings belonged to 61-70 years of their mean is 5, mean percentage is 13.2, median is 5.5, and SD + 1.1. Less similar findings belonged to > 70 years of their mean is 5, mean percentage 12.3%, median is 4.5, and SD + 1.6.

Findings related to Gender.

Graph 2, revealed that, majority of the findings belonged to males of their mean is 22.5, mean percentage is 56.2%, median is 23, and SD + 1.19. Less similar findings belonged to females of their mean is 17.5, mean percentage is 43.7%, median is 18, and SD will be 1.6.

Findings related to BMI status.

Graph 3, revealed that majority of the findings belonged to underweight of their mean is 21.5, mean percentage is 53.7%, median is 22, and SD + 3.7. More or less similar respondents belonged to normal of their mean is 10.5, mean percentage is 26.2%, median is 11.5, and SD + 1.4. Less similar findings belonged to overweight of their mean is 8, mean percentage is 20%, median is 10, and SD + 1.9.

Findings related to Cavitation on chest X-ray.

Graph 4, revealed that, majority of the findings belonged to sputum smear positive (AFB) of their mean 40, mean percentage is 100%, median is 20.5, and SD + 4.3. None of the findings belonged to sputum smear negative (AFB). Majority of the finding belonged to sputum positive molecular test of their mean is 40, mean percentage is 100%, median is 20.5, and SD + 4.5. None of the findings belonged to sputum negative molecular test.

In the present study RTI without adverse drug reactions (Control Group) findings revealed that;

Findings related to age.

Graph 5, revealed that majority of the findings belonged to 51-60 years of their mean is 11.5, mean percentage 28.7%, median is 12, and SD + 2.8. More or less similar findings belonged to < 40 years of their mean is 10, mean percentage 25%, median is 10.5, and SD + 2.4. More or less similar findings belonged to 40-50 years of their mean is 9, mean percentage 22.5%, median is 9.5, and SD + 1.1. More or less similar findings belonged to 61-70 years of their mean is 5, mean percentage 12.5%, median is 5.5, and SD + 1.5. Less similar findings belonged to > 70 years of their mean is 4.5, mean percentage 11.2%, median is 5, and SD + 3.3.

Findings related to gender.

Graph 6, revealed that, majority of the findings belonged to males of their mean is 23.5, mean percentage 58.7%, median is 24, and SD + 1.2. Less similar findings belonged to females of their mean is 16.5, mean percentage 41.2%, median is 17, and SD + 1.1.

Findings related to BMI status.

Graph 7, revealed that, majority of the findings belonged to normal of their mean is 20.5, mean percentage 51.2%, median is 21, and SD + 1.9. More or less similar findings belonged to overweight of their mean is 1.5, mean percentage 27.5%, median is 11.5, and SD + 1.5. Less similar findings belonged to underweight of their mean is 8.5, mean percentage 21.2%, median is 9, and SD + 1.1.

Findings related to Cavitation on chest X-ray.

Graph 8, revealed that, majority of the findings belonged to sputum smear negative (AFB) of their mean is 50, mean percentage is 100%, median 49.5, and SD + 7.7, none of the findings

belonged to sputum smear positive (AFB), and majority of the findings belonged to Sputum negative molecular test of their mean 50, mean percentage 100%, median 49.5, and SD + 7.7.

In the similar study result findings revealed that;

This study was designed to assess the prevalence of hepatotoxicity, including ATLI, among patients receiving intensive-phase anti-TB treatment in the Republic of Congo. The findings revealed significant differences in transaminase levels among patients influenced by demographic and clinical variables, including gender, age, and HIV status.

We observed that 22.6% of patients had elevated ALT or AST levels, but only four patients met criteria for ATLI. These results are comparable to reports from other resource-limited settings: studies in Ethiopia, Nigeria, and Uganda have reported transaminase elevations ranging from 15% to 35%, with ATLI incidence typically 3-10% during the intensive phase of treatment. Differences in prevalence across studies may reflect variations in study design (cross-sectional vs longitudinal), timing of measurement, baseline liver function screening, anti-TB regimens, and population characteristics such as HIV prevalence, hepatitis B virus (HBV)/hepatitis C virus co-infection, alcohol use, malnutrition, and body mass index.

In our study, male patients exhibited significantly higher transaminase levels than females, which is consistent with previous studies. This may suggest sex-based disparities in hepatic drug metabolism and susceptibility to drug-induced liver injury, including hormonal influences and liver enzyme expression patterns. Biologically, male patients often have higher expression of certain cytochrome P450 enzymes, which can alter the metabolism of anti-TB drugs and increase susceptibility to hepatocellular injury, whereas estrogen may confer hepatoprotective effects in females. The observed age-related increase in transaminase levels, with the youngest group showing the lowest median values, may potentially suggest differences in hepatic resilience or cumulative comorbidities. Age-related variations in hepatic regenerative capacity, cumulative exposure to hepatotoxins, and changes in liver enzyme activity may affect drug clearance and susceptibility to liver injury.

ETHICS STATEMENT

All procedures related to data protection and patient privacy were conducted in accordance with applicable regulations and institutional policies. Ethical Consideration I/we hereby declare that there are no ethical concerns associated with the study entitled “Burden of antitubercular drug-induced hepatotoxicity among tuberculosis and other respiratory tract infected patients admitted to a quaternary care hospital, Belagavi.”This study should not harm

to any humans or animals, and informed consent was taken from all participants' prior data collection. The name of the affiliated institution is 'Arihant Institute of Nursing Sciences Belagavi. The ethical committee not found any of the issues in the study and granted us approval for further investigation.

Article Information and Declarations

Data availability statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

Author's Contributions

Dr Ashok Kamat: Conceptualization, investigation, project administration, visualization, writing, original draft preparation, writing, review & editing.

Afrin Naikwadi: Supervision, writing, review & editing.

Manjunath Jadhav: Data tabulation and data analysis through descriptive and inferential statistics

Dada Hayat Sakali: Creation of graphs and interpretation.

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Conflict of interest: No conflicts of interest.

Supplementary material: None.

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