RESEARCH ARTICLE

TRENDS AND CHARACTERISTICS OF SMEAR POSITIVE PULMONARY TUBERCULOSIS IN A TERTIARY CARE HOSPITAL IN NORTH INDIA.

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Manuscript Info	Abstract
	Context: Infection due to tuberculosis is a major public health problem across the world. Pulmonary tuberculosis which is smear positive is highly infectious and a main source of transmission to contacts. **Aims:** This study was undertaken to determine the trends over time in smear positive pulmonary tuberculosis, the demographic profile of patients with pulmonary tuberculosis and their treatment outcome. **Methods and Material:** We retrospectively analyzed smear positive pulmonary tuberculosis patients over a period of 8 years. Patient was diagnosed as smear positive by ZeihlNeelson staining and later by auramine fluorescence staining according to the RNTCP guidelines. Trends over time were analyzed and data such as age, gender, treatment category and outcome of the patients was recorded. **Results:** A total of 447 patients were identified as smear positive pulmonary tuberculosis. The percentage of smear positive cases has decreased to 30% over a period of eight years. Most cases were seen in male gender and most common age group was elderly followed by 21-30 years. Overall treatment success rate was 96.87%. **Conclusion:** This study demonstrates considerable reduction in smear positive pulmonary tuberculosis infection. However further strengthening of the program must be implemented to achieve higher rates of treatment success.

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Introduction:-

Tuberculosis presents a significant health problem and is a major cause of morbidity and mortality all over the world. *Mycobacterium tuberculosis* infects one third of the world population and causes 1.5 million deaths annually (WHO. Global Tuberculosis Report, 2012). India alone accounts for 26% of all the TB cases. Incident cases are 181 per 100,000 population and smear positive cases are 165 per 100,000 population (Sharma and Mohan, 2013)

Tuberculosis is mainly transmitted by inhalation of the infected aerosols. Pulmonary tuberculosis which is smear positive is highly infectious and a main source of transmission of infection to people in the community. It is estimated that an infectious case infects 10-15 individuals per year if left untreated. Early diagnosis and effective treatment of such patients is necessary to control the spread of infection (Zumla et al, 2013).

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This retrospective study spanning 8 years is aimed to determine the trends over time in smear positive pulmonary tuberculosis, the demographic profile of patients with pulmonary tuberculosis and their treatment outcome.

Material and Methods:-
Setting: The study was carried out in SKIMS, a 800 bedded tertiary care hospital that participates under the RNTCP programme.

Collection of samples: sputum samples of patients with symptoms suggestive of tuberculosis were screened by AFB smear microscopy in conformity to the RNTCP guidelines (Revised national tuberculosis programme guidelines for culture and drug susceptibility testing manual, 2012). Patients were given the sputum containers and asked to collect 3 sputum samples (spot-early morning-spot) on 2 consecutive days. From year 2010 onwards, patients were instructed to get 2 sputum samples only (spot- early morning or spot- spot).

Diagnosis by AFB microscopy: all smears were examined in the designated microscopy center by ZeihlNeelson method using conventional microscopy up to the year 2012. From year 2012 onwards, samples were examined with light emitting diode fluorescence microscopy. The grading was done according to the RNTCP guidelines as shown in Table 1. All smear positive patients were classified into 2 groups- new cases or previously treated. Patients were treated as per the revised national technical guidelines.

Demographic Data:-
Data retrieved from the records included identification, age, gender, location, year and month of diagnosis, treatment history and outcome of all smear positive patients. Outcome was recorded as per RNTCP guidelines as:
a.   Cured/ treatment completed- patient registered as pulmonary smear-positive, completed treatment
b.   Default-Has not taken drugs for more than 2 months consecutively any time after starting treatment
c.   Failure-Was registered as pulmonary smear-positive CAT II (retreatment), and was smear-positive at five months or later of CAT II treatment or
d.   Died-Was known to have died from any cause whatsoever while on treatment

Data Analysis:-
Data was entered in a Microsoft excel sheet. It was a retrospective study. Categorical variables was summarized as frequency and percentage. Continuous variables was summarized as mean and standard deviation. Data analysis was done using EpiInfo 7.0.

Results:-
During the 8 year study period, 11857 patients with symptoms suggestive of tuberculosis were examined. 1006 patients were diagnosed with tuberculosis (both pulmonary and extrapulmonary). Of these, a total of 447 were identified as smear positive pulmonary tuberculosis. The trend in the percentage of smear positive tuberculosis over a period of eight years is shown in figure 1. Based on the visual analysis of the trends in percentage, 3 distict time periods are noted: a) mildly increasing trend (from year 2009-2012); b) steadily declining trend (between years 2012- 2015); and c) rapidly decreasing trend (from 2015 to 2016).

Table 1:- Grading of smears according to RNTCP guidelines.

WHO scale Result	Bright Field microscopy (100X) 1 length= 2cm= 100 OIF	Fluorescence Microscopy (40X) 1 length= 40 fields
Negative	Zero AFB/ length	Zero AFB/ length
Scanty	1 - 9 AFB/ length	1 - 19 AFB/ length
1 +	10 - 99 AFB/ length	20 - 199 AFB/ length
2 +	1 - 10 AFB/ length	5 - 50 AFB/ length
3 +	> 1 0 AFB/ length	> 5 0 AFB/ length

The descriptive characteristics in terms of age and gender are shown in table 2. The disease was prevalent more in males than females over the years. Maximum cases were seen in the elderly population followed by age group of 21-30 years and this trend was consistent over this 8 year period.

The category of patients and their outcome is shown in table 3. New cases were more than previously treated cases. However the proportion of previously treated cases increased consistently. No case of default or failure was seen until 2012. Subsequently 2, 1 and 3 default cases were seen in years 2013, 2014 and 2016 respectively.

Table 2:- Descriptive characteristics of patients.

	2009	2010	2011	2012	2013	2014	2015	2016
Males	37	28	24	21	24	40	40	40
Females	22	18	22	16	14	20	25	27
11-20	8	6	13	8	9	9	9	8
21-30	19	9	10	7	18	16	18	20
31-40	4	6	4	5	7	7	7	7
41-50	10	9	5	4	8	8	8	8
> 50	18	16	14	13	25	20	23	24

Table 3:- Distribution of patients according to category and treatment outcome

Year	2009	2010	2011	2012	2013	2014	2015	2016
New	53	43	41	23	40	48	51	46
Previously treated	6	3	5	14	27	12	14	21
Cured	59	46	45	37	65	56	64	61
Default	0	0	0	0	2	2	0	3
Failure	0	0	0	0	0	1	0	1
Died	0	0	1	0	0	1	1	2
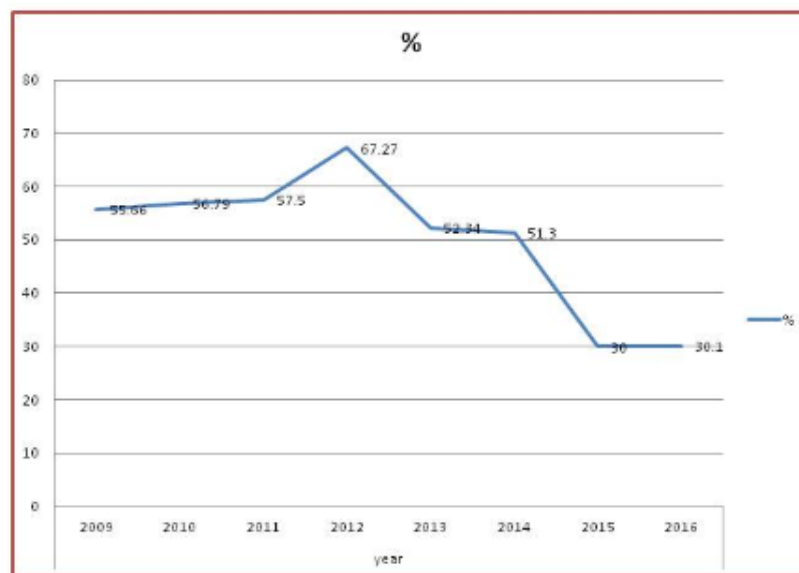
Fig 1:- Percentage of pulmonary tuberculosis that was smear positive, 2009 to 201

Discussion:-

During the 8 year study, we found about 447 cases of smear positive pulmonary tuberculosis patients. There has been a modest increase in the rate of smear positive cases from year 2009 to 2012 but the percentages have considerably decreased thereafter. A significant decline of 25% has been noted in 8 years. This is higher than the average decline in smear positive tuberculosis seen in other studies (Kolappan et al,2013). The decline can be attributed to overall strengthening of the TB control practices due to political commitment, implementation of DOTS strategy with quality assured sputum microscopy and DOTS therapy.

In our study, the disease was more frequent in males as compared to females. Higheracquisition among males is consistent with other studies reporting male gender and smoking as a risk factor for tuberculosis acquisition.(Chada et al, 2012)

Highest number of patients was seen in the age group of > 50 yrs followed by 21-30 years. Although tuberculosis is a disease of young adults, higher proportion of the disease in the elderly could be attributed to reactivation of latent infection.

An alarming trend of increase in previously treated cases has been noted for the last 8 years. This is a matter of concern as the pill burden as well as the duration of treatment is prolonged. A cure rate of 100% was achieved in the year 2009 to 2012. Only one patient died during the therapy due to associated co-morbid conditions. 7 cases of default, 2 cases of failure and 4 deaths were reported from 2013 to 2016. Overall success rate was 96.87%. Failure rate was 1.67% in the year 2014 and 1.5% in 2016. Our success rate is higher as compared to other studies. In a study by Chadda et al, the cure rate was 91% and 73.3% for Cat 1 and Cat II patients respectively. A study by Karanjayker showed an overall treatment success rate of 87%. A high success rate could be attributed to low default rate in our patients included in the study. (Karanjayker, 2014)

A limitation of this study is that this is a hospital based study and therefore is based upon passive case detection. The actual prevalence of disease in the community cannot be estimated.

In conclusion there has been a considerable reduction in smear positive pulmonary tuberculosis infection. Anti tuberculosis treatment under RNTCP has enabled to treat the patient under DOTS strategy and therefore the patient can be followed until the completion of therapy. To further reduce the disease prevalence, further strengthening of the program must be implemented to achieve higher rates of treatment success.

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