A Study to Assess Ototoxicity in Patients Receiving Anti-Tubercular Therapy

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Abstract: Objectives: To assess the incidence of ototoxicity in patients receiving ATT. To assess the onset of clinical symptoms of ototoxicity with pure tone audiometry findings. To assess whether the ototoxicity is reversible or irreversible. Materials and Methods: A prospective observational study was conducted in 100 patients who were diagnosed with tuberculosis. Follow-up was carried out at intervals of 2 months from the initiation of treatment until its completion. After the completion of the treatment, patients identified with ototoxicity were followed up for a year to note PTA.

Method of Statistical Analysis

The results were presented in number and percentage for dichotomous data in Table and Figure. Univariate analyses of the dichotomous variables encoded were performed by means of the Chi square test with Yates correction if required. In all the above tests the “p” value of less than 0.05 was accepted as indicating statistical significance.

Results

Most of the patients enrolled in the study were in 40-49 years, 32 patients. Next common age group affected was 50-59 years. Male predominance is found in our study. Male: Female ratio is 1.6:1. Giddiness, Headache, Nystagmus and Tinnitus are present in 20, 25, 7 and 15 patients respectively by the end of 2 months during the course of treatment. Decreased hearing is commonly seen by the end of 2nd month, 20%, which gradually increased to 21% by end of the course of treatment. On PTA findings 15 Male and 5 female patients had HFL by the end of 2nd month (p value -0.274). On 1-year follow-up 21 patients had irreversible hearing and HFL in the PTA report.

After the completion of the treatment, patients identified with ototoxicity are followed up for a year to note PTA.

1. Introduction

Tuberculosis (TB) is a bacterial infection caused by mycobacterium tuberculosis complex¹. WHO declared TB as a global emergency in 1993 ¹. Incidence of active pulmonary tuberculosis in India is estimated to be as high as 3 million new cases per year worldwide¹. Rifampicin(R) (450mg), Isoniazid(H) (300mg), Pyrazinamide(Z) (1500mg), Ethambutol(E)(1200mg), and Streptomycin(S)(750mg) are the primary anti-tubercular drugs used ³. Toxicity to the auditory and vestibular system is a well-known complication in Anti – Tubercular Therapy (ATT) ³. Ototoxic complaints seen in this therapy are dizziness, tinnitus and hearing loss ³. Alteration in drug regimen following early detection of hearing loss by Pure Tone Audiometry (PTA), prior to its clinical presentation helps curtail further loss of hearing before it can adversely affect the ability to communicate.

2. Materials And Methods

A prospective observational study was conducted in the department of ENT, Kempegowda Institute Of Medical Sciences, Bangalore from June 2015 till January 2017. 100 patients who were diagnosed with tuberculosis and met the inclusion criteria, were selected for the study. Inclusion Criteria was:

1) Adults of both sexes aged 18-60 years
2) Patients having Tuberculosis (New extra pulmonary, Relapse, Failure, Default)
3) Newly enrolled at the study centre for the DOTS therapy
4) No evidence of hearing loss prior to the commencement of treatment
5) Informed written consent

Prior to initiation of therapy at our center, all patients had undergone detailed vestibular and cochlear function evaluation. Follow up was carried out at intervals of 2 months from the initiation of treatment until it’s completion.
month. This result was persistent throughout the course of treatment. 15 (23.8%) male patients had hearing loss in PTA during follow up. 6 (16.21%) female patients had hearing loss during follow up. This PTA result was persistent for 1 year follow up. P value – 0.441. The most common age group affected was 40-49 years (66.6%) had decreased hearing loss during follow up. The next group effect was 50-59 years, 5.5%. This result was persistent till 1 year follow up. 15 (23.8%) male patients had hearing loss during follow up. 6 (16.21%) female patients had hearing loss during follow up. This result was persistent for 1 year follow up. P value – 0.441.

6. Conclusion

Streptomycin plays a major role in the management of multidrug resistant mycobacteria. Toxicity to the auditory and vestibular system is a well-known common complication of the treatment with aminoglycoside antibiotics. In the present study, the incidence of ototoxicity was 21%. Similar results were seen in a study conducted by Khatijah et al which had hearing loss in 33% of patients. Duggal et al. studied ototoxicity caused by streptomycin and also showed similar results, 18.7% of patients had hearing loss. In contrast, a study conducted by De Jager et al. showed 30% of patients (60%) treated with streptomycin eventually developed ototoxicity. Similar high incidence of ototoxicity was reported in a prospective study of 53 patients by Fausti et al., 47%. Similarly, in a study conducted by De Lima et al., where hearing sensitivity of 36 cured TB patients who had been treated with streptomycin was assessed, findings indicated that 75% of the participants presented with auditory disorders. De Lima et al. reported that of those patients who presented with auditory disorders (75%), 85% presented with bilateral HFL. In our current study all 21 patients had bilateral HFL. However, the precise incidence of ototoxicity remains controversial. Study conducted by Sharma et al showed that most of the patients developed hearing loss during 4-5th week of therapy. Study conducted by B.E. Gulbay et al in their study showed Ototoxicity appeared on 25±8.1 day of treatment (14-46 days). Study conducted by Gulbay et al had Tinnitus (in 9 patients), dizziness/vertigo (in 5 patients), loss of balance (in 3 patients) and hearing disturbance (in 2 patients) were recorded in the ototoxicity group. Khatijah et al. reported that symptoms such as tinnitus, vertigo, nausea and hearing loss will wear off and no further investigations or follow-up were recommended. In the present study there was no recovery of hearing loss, all 21% of patients had irreversible hearing loss, till 1 year follow-up. Similarly, Duggal et al in his study noticed that hearing loss once developed has been found irreversible and none of the patients showed improvement till 1 year follow up.

5. Discussion

MDR-TB is a growing problem throughout the world. Streptomycin plays a major role in the management of multidrug resistant mycobacteria. Toxicity to the auditory and vestibular system is a well-known common complication of the treatment with aminoglycoside antibiotics. Audiologic changes have been reported in patients of MDR-TB using streptomycin which can potentially affect the communication ability of the patients. But careful early audiologic monitoring may help in limiting this damage which once developed is permanent.

References


