

## ADVERSE REACTIONS TO GENTAMYCIN IN PATIENTS WITH EAR, NOSE OR THROAT INFECTIONS\*

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( Received on February 15, 1992 )

**Abstract:** Eighty four patients requiring treatment with Gentamycin were selected from Otorhinolaryngology outpatient and those admitted to the hospital. Patients suffering from hepatic or renal disorders, pregnant women and children were excluded from the study. Seventy three were administered gentamycin 40 mg BD intramuscularly for 7-10 days and in 11 the drug was applied topically as ear drops for 6-12 weeks. Adverse reactions were observed in 9 (13.3%) and 11 (100%) patients given the drug parenterally and topically respectively. In parenteral group incidence was higher in females as compared to males and profile included nausea and vomiting, headache, cough, tinnitis, albuminuria, diminution of hearing and vertigo. Whereas diminution of hearing acuity was observed in all those who had topical application as evidenced by pure tone audiometry.

**Key words:** gentamycin                      adverse reactions                      ototoxicity

### INTRODUCTION

Gentamycin, an aminoglycoside antibiotic, is commonly administered for the treatment of infections due to gram negative and some gram positive bacteria. While its adverse reactions (ADR) have been extensively studied and recognized (3), the data related to Indian population is not documented.

The present study was designed to detect ADR profile of gentamycin in patients requiring treatment with the drug in Ear, Nose and Throat infections.

### METHODS

84 patients of either sex between 25-46 yrs of age were selected from outpatient, and those admitted to the ward of Otorhinolaryngology Department, J.N. Medical College Hospital, A.M.U., Aligarh. The selection criteria were bacterial infections of ear, nose and throat, exhibiting sensitivity to gentamycin *in vitro*. Exclusion criteria were associated hepatic or renal disorders, pregnancy and children.

A short history of the patients regarding their

present illness and any relevant past and family history was taken. A note of any treatment taken prior to reporting to the hospital was made. Investigations carried out included haematological profile, hepatic and renal functions and pure tone audiometry.

73 patients were administered gentamycin in a dose of 80 mg twice a day intramuscularly for periods extending from 7 to 10 days. Another group of 11 patients suffering from chronic suppurative otitis media (CSOM) was given gentamycin topically as ear drop for a long time (6-12 weeks). Besides gentamycin, no other drug except paracetamol was given simultaneously, if required. Patients were examined on alternate days and questioned specifically to detect appearance of any adverse reactions.

### RESULTS

Adverse reactions to intramuscular administration to gentamycin were observed in 9 (13.3%) of the 73 patients so treated (Table I). All the ADR's were observed more in females as compared to males. Nausea and vomiting was observed only in one female patient while cough was observed only in two male patients.

\*Paper was awarded Harish Gupta Prize for 1991 at 37th Annual Conference of A.P.P.I. held at Bangalore.

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TABLE I: Showing incidence of ADR's due to gentamycin administered by intramuscular route in a dose of 40 mg BD for 7-10 days.

	<i>Male</i>		<i>Female</i>		<i>Total</i>	
	<i>No.</i>	<i>%</i>	<i>No.</i>	<i>%</i>	<i>No.</i>	<i>%</i>
Total patients	48	66	25	34	73	—
No. of patients with ADR	5	10.4	4	16	9	12.3
<b>ADR Profile</b>						
Nausea and vomiting						
	1	2	2	8	3	4.1
Headache						
	—	—	1	4	1	1.36
Cough						
	2	4.16	—	—	2	2.7
Albuminuria						
	1	2	2	8	3	4.1
Diminution in hearing						
	3	6.25	2	8	5	6.8
Vertigo						
	2	4.16	2	8	4	5.48
Tinnitus						
	2	4.16	3	12	5	6.8

Adverse reactions observed following topical application of gentamycin in patients of chronic suppurative otitis media are summarized in Table II. All the patients included in the study experienced one or the other adverse reactions.

TABLE II: No. of Adverse Reactions observed in patients administered parenteral gentamycin according to sex.

<i>No. of ADR's</i>	<i>Male</i>	<i>Female</i>
No. of patient with ADR	5	4
One	1	—
Two	2	1
Three	2	2
Four	—	1

## DISCUSSION

Adverse reactions to antimicrobial agents are well known but their exact incidence in Indian population is not well documented (7). Several antibiotics are

capable of causing oto and other toxicities. However, it is the aminoglycoside group of antibiotics which are the main offenders (8, 12, 13).

Gentamycin is frequently used in hospitals and general practice for treating the gram negative and other bacterial infections of ear, nose and throat. On parenteral administration for a short period (7-15 days) gentamycin caused a number of adverse reactions (Table I), although the main manifestation was vestibular and cochlear dysfunction (2, 9, 11).

Parenteral administration of gentamycin produced cochlear and vestibular damage in 6.8 and 5.48 percent cases respectively. The toxicity has been observed variably and depends on the dose and duration of the drug administered (4, 6). High frequency hearing loss was detectable by audiometric examination (6.8%) and was the early sign of cochlear toxicity. Vestibular toxicity was assessed by electronystagmography and was 5.48% in the present study. The higher incidence of ADR's was observed in females. It is difficult to assign any cause to this finding. However, further



studies are required to verify the veracity of this observation.

Ototoxic antibiotics gain access to the fluids of the inner ear by way of the blood stream, either directly by intravenous administration, or secondarily following intramuscular injection, absorption from the gut, or topical application to denuded skin and mucosa (1).

Following topical application of aminoglycosides to the mucosa of the middle ear cleft, the drug may reach the organ of Corti by passing through the round

window membrane or annular ligament to the perilymph in the scala vestibuli and through Reissner's membrane into the endolymphatic space in the scala media. The hair cells are therefore exposed to high levels for a long time on topical application of gentamycin. This may cause sensori-neural deafness in patients of chronic suppurative otitis media (CSOM) which are already having conductive hearing loss (1, 10). The present study showed sensori-neural deafness in four patients of CSOM on prolonged use of gentamycin and the loss of hearing ranged from 30 to 80 dB at higher frequencies (Table III). A typical audiogram of the patient is appended (Fig. 1).

TABLE III : Showing incidence of ADR's due to gentamycin administered topically for periods ranging from 6-12 weeks.

ADR	Male		Female		Total	
	No.	%	No.	%	No.	%
Total patients	7	-	4	-	11	-
Tinnitus	2	28.5	1	25	3	27.2
Contact Dermatitis	1	14.2	1	25	2	18.1
Headache	2	28.5	0	-	2	18.1
Diminution of hearing	2	28.5	2	50	4	27.2

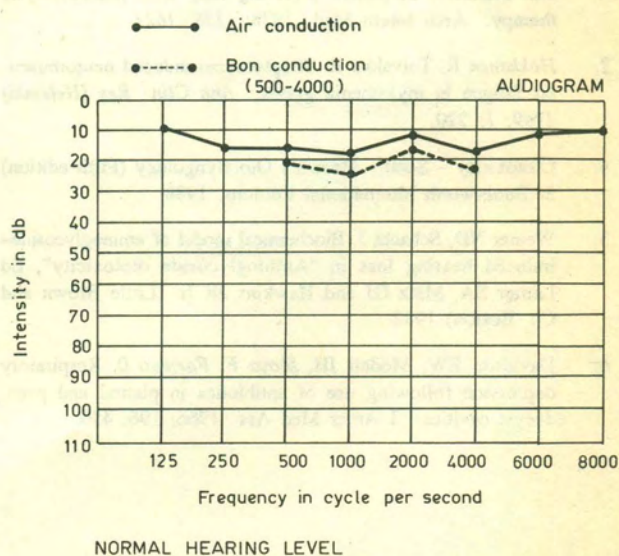
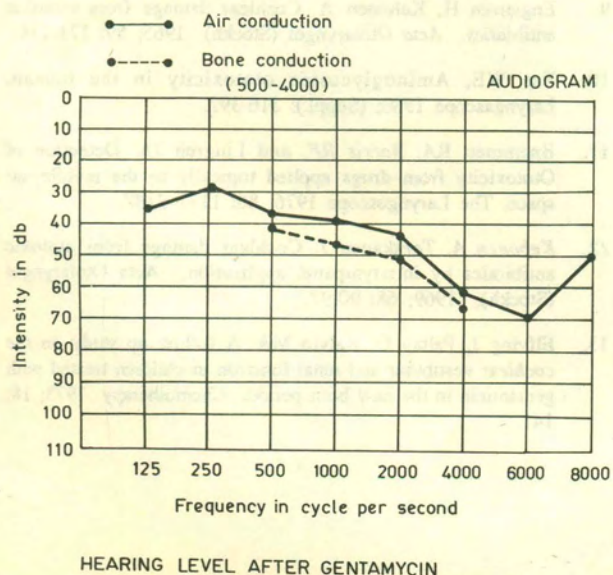


Fig. 1.



Gentamycin is the most nephrotoxic of the commonly used aminoglycosides followed by amikacin and kanamycin (11). Duration of therapy and dosage administered generally determines the incidence of renal damage. The patient may present with albuminuria or hematuria (5, 11). In the present study 4 patients (5.4%) developed albuminuria. Following dechallenge urine became free of albumin thus suggesting that the damage, if any, caused to kidneys was temporary and self limiting. However, greater caution is required for the use of aminoglycosides in general and gentamycin in particular in patients with potential or impending renal damage and also in females who are more predisposed to urinary tract infections and consequently renal damage. It is imperative that periodic urinary analysis be conducted and gentamycin be stopped on appearance of any evidence of renal damage (13).

Other adverse reactions observed included nausea, vomiting, and cough which may be attributed to hypersensitivity to the drug. Topical application of gentamycin may cause contact dermatitis. More data are required to substantiate the finding that the incidence of ADR's is higher in females as compared to males.

The drug should not be used in CSOM where chances of its gaining access into the internal ear are very high resulting in further loss of hearing.

#### ACKNOWLEDGEMENTS

The study is a part of Multicentric Project entitled "Monitoring of Epidemiological profile and factors responsible for Adverse Drug Reactions in India". Authors are thankful to Indian Council of Medical Research.

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