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## ROLE OF NASAL DECONGESTANTS IN SPONTANEOUS HEALING OF TRAUMATIC TYMPANIC MEMBRANE PERFORATION

**Objective:**

To study the role of nasal decongestants in spontaneous healing of traumatic tympanic membrane perforation.

**Material and Methods:**

A prospective single blinded, randomized controlled study was carried out in the department of ENT, Manipal College of Medical Sciences, Pokhara, Nepal. Patients with traumatic tympanic membrane perforation were divided into two groups; those receiving nasal decongestants along with conservative measures (Group1) and those receiving conservative measures only (Group2). Healing of tympanic membrane was compared in between these groups at 1 and 3 months. Statistical analysis was done using SPSS 20.

**Results:**

There were 30 patients in group 1 and 28 patients in group 2. The mean age of the study population was 26.98 (SD= 7.53). The M: F ratio in group 1 was 0.58:1 and that in group 2 was 0.56:1. Complete healing was seen in 25 (83%) patients in group 1 and 16 (57.1%) patients in group 2 at the end of 1 month (P=0.029). Similarly, healing was seen in 29 (96.7%) patients in group 1 and 21 (75%) patients in group 2 at the end of 3 months (P=0.023).

**Conclusion:**

Routine use of nasal decongestants increases the chances of spontaneous healing of traumatic tympanic membrane perforations.

**Keywords:** Eustachian tube, Nasal decongestants, Spontaneous healing, Tympanic membrane perforation

### INTRODUCTION:

Traumatic perforation of the tympanic membrane (TM) is a common entity and can be caused by either direct trauma to the TM (self cleaning with pins, matchsticks; iatrogenic trauma etc.) or barotrauma i.e. trauma caused by sudden build of negative pressure in the middle ear (slap, swimming, flight landing etc.). Majority (80%) of Traumatic TM perforations heal spontaneously if a favorable environment is created for them.<sup>1</sup> For this purpose, the ear should be kept dry by inserting cotton ball with petroleum jelly into the ear while taking shower, avoid blowing the nose and prevent secondary infection. Surgical remedies like myringoplasty are indicated if spontaneous healing does not occur till 2-3 months.<sup>1, 2</sup> Two main factors leading to failure of spontaneous healing are loss of tissue and secondary infection.<sup>3</sup> It is thus imperative to promptly treat any infection in the course of healing of TM perforation. Eustachian tube (ET) block is the commonest cause of middle ear infection and it in turn impairs the spontaneous healing of TM. Eustachian tube has a very important role to play in spontaneous healing of traumatic TM perforation. It connects the middle ear to the nasopharynx and acts as a pressure equalizer of the middle ear. If the ET gets blocked, it leads to middle ear infection, which in turn impairs the spontaneous healing of TM and causes permanent perforation of TM requiring surgery in later aspect of patient's life.<sup>4</sup> In this study we have used oral as well as topical nasal decongestants to prevent ET blockade in a subset of patients with traumatic TM perforation along with all the conservative measures that were used in other subset. Spontaneous healing of TM was evaluated and analyzed amongst the two groups at the end of 1 month and 3 months.

### MATERIAL AND METHODS:

A prospective single blinded, randomized controlled study was carried out in the department of ENT-HNS Manipal College of Medical Sciences, Pokhara, Nepal with an aim to study the role of nasal decongestants in spontaneous healing of traumatic tympanic membrane perforation. The study duration was from January 2013 to March 2014. All patients with history of traumatic tympanic membrane perforation were examined thoroughly in the ENT OPD and were randomized into two groups: Group 1 consisted of patients in whom nasal decongestants were used along with preventive measures whereas Group 2 consisted of patients where preventive measures were only used. Patients were explained regarding the preventive measures which include: avoiding instillation of oil or any type of ear drops in the ear, plugging the ears with cotton ball coated with petroleum jelly while bathing, avoiding swimming and cold food

items.

Randomization was done according to the days of the week; patients presenting on odd days (Sunday, Tuesday, Thursday) were enrolled in group 1 and those presenting on even days (Monday, Wednesday, Friday) of the week were enrolled in group 2. After a detailed ENT examination, all the patients were subjected to hearing assessment with PTA (Pure Tone Audiometry) at the beginning of the study. Treatment was based on conservative strategy and nasal decongestant for group 1 and conservative management only in group 2. Patients were followed up every 2 weeks for 1 month then every month for 3 months. At each follow up thorough examination was carried out to evaluate the state of healing. Those patients showing no features of spontaneous healing at the end of 3 months were advised for surgery. Data were collected in pre-structured chart in terms of patient's characteristics (age, gender); clinical characteristics (duration of injury, causes of injury, clinical features, size and side of perforation etc.) and state of healing at the end of 1<sup>st</sup> and 3<sup>rd</sup> month. The site of perforation was classified as antero-superior, antero-inferior, postero-superior, postero-inferior and central (if more than one quadrant was involved). Statistical analysis was done using SPSS 20 to analyze the difference in healing between the two groups at the end of 1 month and 3 months using Chi Square test and Fischer Exact test. Patients of both sex and all ages were included in the study. All the patients were explained thoroughly about the study and other options of treatment. An approval was taken from the institutional ethical committee and an informed consent was taken from all the patients before enrolling them into the study. Those patients not opting for conservative management, having preexisting ear discharge, with past history of middle ear disease or any form of ear surgeries in the past were excluded from the study.

### RESULTS:

A total of 58 patients were included in the study. The mean age of the study population was 26.98 (SD= 7.53). The mean age of participants in the study group 1 was 26.9 (SD=6.9); and that of study group 2 was 27.1 (SD=8.19). Our study population comprised predominantly of females with male to female ratio (M: F) of 0.57:1. The M:F ratio in group 1 was 0.58:1 and that in group 2 was 0.56:1. The mean duration of injury at presentation to the hospital was 4.14 days (SD=3.22). Table 1 shows the main clinical characteristics of the patients under study. Decreased hearing (70.7%), tinnitus (34.5%) and earache (29.3%) were the most common symptoms at presentation (Table 2). In our study we also inquired about type of injury sustained. Twenty six patients out of fifty eight (44.8%) were due to physical abuse

Table 1. Patient and Clinical Characteristics

Parameters	GROUP1 (%)	GROUP2 (%)	TOTAL (%)
Mean Age (SD)	26.90(6.99)	27.07 (8.19)	26.98 (7.53)
Sex			
Male Female	11 (36.7) 19 (63.3)	10 (35.7) 18 (64.3)	21 (36.2%) 37 (63.8%)
Mean Days at Presentation	4.23 (3.37)	4.04 (3.11)	4.14 (3.22)
Laterality			
Right Left Bilateral	9 (30) 16 (53.3) 5 (16.7)	10 (35.7) 14 (50) 4 (14.3)	19 (32.8%) 30 (51.7) 9 (15.5)
Causes of Trauma			
Barotrauma Direct Trauma	25 (83.3) 5 (16.7)	24 (85.7) 4 (14.3)	49 (84.5) 9 (15.5)
% of TM Perforation			
20	17 (56.7)	15 (53.6)	32 (55.2)
40	6 (20)	7 (25)	13 (22.4)
60	6 (20)	6 (21.4)	12 (20.7)
80	1 (3.3)	0 (0)	1 (1.7)
Edges			
Inverted			
Everted	23 (76.7) 7 (23.3)	22 (78.6) 6 (21.4)	45 (77.6) 13 (22.4)
Type of Hearing Loss			
Conductive	27 (90)	27 (96.4)	54 (93.1)
SNHL	2 (6.7)	1 (3.6)	3 (5.2)
Mixed	1 (3.3)	0 (0)	1 (1.7)
Mean PTA (dB)	28.70 (4.48)	28.21 (3.90)	28.47 (4.18)

(mainly slap injury). Slap injury was seen more frequently in females (80.8%) than in males (19.2%). Swimming, self-cleaning, iatrogenic trauma during otological procedures etc. were the other causes of traumatic perforation of the TM (Table 3). The posterior half of the tympanic membrane was the most commonly involved area (79.3%) and the postero-inferior quadrant was the most commonly involved quadrant (48.3%). The antero-inferior quadrant was perforated in 12.1% of cases (Table 4). When followed up at 1 month, healing was seen in 25 (83.3%) of cases in group 1 and 16 (57.1%) of cases in group 2 and the difference was statistically significant (P=0.029). At 3 months there was 29 (96.7%) and 21 (75%) of cases with healed TM perforation in group 1 and group 2 respectively and the difference was still statistically significant (P=0.023) (Table 5).

Table 2. Symptoms at presentation

Symptoms	GROUP1 (%)	GROUP2 (%)	TOTAL (%)
Tinnitus	9 (30)	11 (39.3)	20 (34.5)
Ear Bleed	5 (16.7)	4 (14.3)	9 (15.5)
Vertigo	3 (10)	4 (14.3)	7 (12.1)
Impaired Hearing	22 (73.3)	19 (67.9)	41 (70.7)
Earache	8 (26.7)	9 (32.1)	17 (29.3)

**DISCUSSION:**

Traumatic Perforation of the TM is a common problem seen in ENT practice with an incidence estimated around 6.8 per 1000 and an annual incidence of around 1.4-8.6 per 100,000 populations.<sup>5,13</sup> Most of the traumatic TM perforations heal spontaneously and those, which fail to heal by 2-3 months, should be repaired surgically.<sup>1-2</sup> The rate of spontaneous healing ranges between 48-94%.<sup>6-11</sup> Griffen reported 90% spontaneous healing of TM perforation within 3 months of injury.<sup>12</sup> Kristensen reported 78.7 % spontaneous healing within 2 weeks of injury whereas Chun et al reported 76% of complete spontaneous healing within 3 weeks.<sup>7,13</sup> The rate of spontaneous healing in our series was 70.69% at the end of first month and 86.21% at

Table 3. Mode of Injury

Mode of Injury	Group 1(%)	Group 2(%)	Total(%)
Slap	11 (36.7)	15 (53.6)	26 (44.8)
Swimming	6 (20)	9 (32.1)	15 (25.9)
Self Cleaning	6 (20)	2 (7.1)	8 (13.8)
Iatrogenic	3 (10)	0 (0)	3 (5.2)
RTA	2 (6.7)	2 (7.1)	4 (6.9)
Flight	2 (6.7)	0 (0)	2 (3.4)

Table 4. Site of Perforation

Site of Perforation	Group 1 (%)	Group 2 (%)	Total (%)
Anterio-Inferior	2 (3.4)	5 (8.6)	7 (12.1)
Posterio-Inferior	14 (24.1)	14 (24.1)	28 (48.3)
Posterio-Superior	4 (6.9)	1 (1.7)	5 (8.6)
Central	10 (17.2)	8(13.7)	18 (31.03)

the end of third month, which is within the range reported in the literatures. Most of the patients in our series were young females (mean age 26.98) and the most common cause of injury was slap injury (44.8%). This is mainly due to prevalence of domestic violence and child abuse in our society. Lindeman et al<sup>14</sup> and Berger et al<sup>15</sup> also reported higher incidence of traumatic TM perforation amongst young females as in our series while Camintz et al<sup>16</sup> reported high prevalence in males. The most common side affected was the left side (51.7%) in our series while right ear was injured in 32.8% of cases and bilateral involvement was seen in 15.5 % of cases. This may be because of the fact that most of the populations are right handed and while slapping caused an impact on the left ear. Al-Obiedi SH, Lindeman, Berger also had similar predilection for the left ear.<sup>5,14,15</sup> Most of the patients in our series (55.2%) had small perforation with involvement of around 20% of the TM size. Large perforation involving 80% of TM size was seen only in 1.7% cases. Most of the studies on TM perforation have reported a prevalence of small sized perforation as in our series.<sup>14,15,17,18</sup> The most common quadrant to be involved was postero-inferior quadrant (48.3%) followed by central quadrant (31%). Sarojamma et al<sup>19</sup> also report higher involvement of the postero-inferior quadrant whereas Korkis et al<sup>20</sup> believed that antero-inferior quadrants were affected more in cases of traumatic TM perforation. Postero-inferior quadrant is more susceptible in cases of direct trauma as it is more laterally placed and more accessible. In our series 45 patients (77.6%) had inverted margins and 13 patients (22.4%) had everted margins of perforations. Al-Obiedi SH also reported higher incidence of inverted than everted margins in his series.<sup>5</sup> The higher incidence of inverted margins of perforation is due to the flow of pressure waves after trauma that travels from outside to inside in most of the cases. In our series, 54 (93.1%) cases had conductive hearing loss, 3 (5.2%) had sensori-neural hearing loss (SNHL) and 1 (1.7%) patient had mixed hearing loss. TM Perforation causes

Table 5. Comparison of TM Healing

S.No	Parameters	Group 1(%)	Group 2(%)	P value
1	Healing at 1 month	25 (83.3)	16 (57.1)	0.029*
2	Healing at 3 months	29 (96.7)	21 (75)	0.023*

\* Significant

conductive hearing loss due to loss of ossicular coupling. The ossicular coupling is lost due to loss of sound pressure difference across the tympanic membrane, which provides the primary drive for movement of the eardrum and ossicles. Perforation of tympanic membrane usually causes a loss that ranges from negligible to 50 dB.<sup>4</sup> In our series the mean hearing level was 28.47 dB (SD= 4.18). The most common presentation was decreased hearing (70.7%) followed by tinnitus (34.5%), earache (29.3%), ear bleed (15.5%) and vertigo (12.1%). Other workers in traumatic tympanic membrane perforation have also reported decreased hearing and tinnitus as the two major findings.<sup>15,17</sup> Spontaneous healing of traumatic TM perforation is affected by presence of persistent ET dysfunction, exposure of the middle ear cavity to water and chronic infections, as they retard the healing process of the tympanic membrane.<sup>2</sup> Thus it is imperative to avoid exposing the involved ear to water by using petroleum jelly coated cotton while taking bath and avoid swimming till the TM is healed to prevent infections. Chronic nose and sinus problems should also be evaluated. The eustachian tube dysfunction has to be treated if present and prevented as far as possible to avoid middle ear infection.<sup>7,21</sup> In this study we prescribed oral as well as topical nasal decongestants to all patients in group 1 with an idea to prevent eustachian tube blockade thus avoiding middle ear infection. At 1 month, 25 (83.3%) patients in group 1 showed complete healing whereas only 16 (57.1%) patients in group 2 showed complete healing and the difference was statistically significant ( $p=0.029$ ). At 3 months, 29 (96.7%) patients in group 1 showed complete healing whereas only 21 (75%) patients in group 2 showed complete healing and the difference was still statistically significant ( $p=0.023$ ). As there is sudden and repeated change in the weather scenario in our region, our patients are frequently subjected to eustachian tube dysfunction due to common cold. This factor might have compromised the healing of traumatic TM perforation in group 2 of our study population, where no nasal decongestants were used.

#### CONCLUSION:

Use of oral and nasal decongestants in our study helps create a favorable environment for spontaneous healing of traumatic TM perforation. Thus from this study we concluded that routine use of nasal decongestants increases the chances of spontaneous healing of traumatic tympanic membrane perforations.

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