

Risk Factors for Patients Undergoing Tympanoplasty

Amal Ahmed Mohamed and Entisar Gaad-Elmoula Shabaan

Department of Medical Surgical nursing, Faculty of nursing Aswan University - Egypt

Abstract: Perforated eardrum can come from a bad ear infection; tympanoplasty is an operation to eradicate disease in the middle ear and to reconstruct the hearing mechanism. Preoperative assessment is very important, to detect factors that can cause postoperative complications. **Aim** to, assessment risk factors for patient undergoing tympanoplasty. **Subjects and Methods:** The study sample was composed of 200 adult patients. The study was conducted at the Upper Egypt Aswan university hospital outpatient clinic and department of Ear Nose and Throat. Data were collected by utilizing the designed assessment sheet, which consist of demographic and medical data tool and risk factor assessment tool. The patients were between 18 and 62 years old and were undergoing tympanoplasty during 2013-2014. **Results:** The study findings revealed that complications occurred in 29.5% of patients in age group 40 to 50 years old, 53.0% of female patients, and 57.0% illiterate patients. Furthermore, less than half of the patients were passive smoking (41.5%). Also, significance difference with low level of hygienic care unclean (67.3%). With significance with poor socioeconomic statuses (75.04%). In the light of the study finding, it is **concluded** that, factors indicating significant were, middle age group, female gender, and low level of educational, regarding hygienic care wear bad habits, Passive smoking and poor socioeconomic status. **Recommendation**, this patient's needs establishing health educational program post tympanoplasty to improved patients outcome. [Amal Ahmed Mohamed and Entisar Gaad-Elmoula Sabaan. **Risk Factors for Patients Undergoing Tympanoplasty.** *J Am Sci* 2015;11(11):204-211]. (ISSN: 1545-1003). <http://www.jofamericanscience.org>. 22. doi:10.7537/marsjas111115.22.

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1. Introduction:

Tympanoplasty is most commonly performed for tympanic membrane perforations greater than 10 to 20% of the size of the entire tympanic membrane. It can arise as sequel of acute otitis media or chronic otitis media with or without cholesteatoma, as a complication of ear perforation tube insertion, or as a result of barotrauma to the ear⁽¹⁾.

Incidence of tympanoplasty in the general population is unknown. One survey found that that 4% of a population of Native American had Tympanoplasty. Another study found that 3% of person treated with ventilation tubes had the condition⁽²⁾.

Chronic suppurative Otitis media still remains an important health problem in the society. The incidence of chronic suppurative Otitis media, 29.7% in the general populations shows the demand for the availability of medical services. The incidence of reporting of the disease is more common in the females and willingness to undergo surgery is also found more common in them. It may be because of the improved social interaction of females in the present day situations⁽³⁾.

High rates of chronic otitis media have been attributed to overcrowding, inadequate housing, poor hygiene due to transmission of the pathogens by physical contact with a contaminated individual, inhalation of infected droplets, or contact with an infected surface, lack of breastfeeding, poor nutrition,

passive smoking, anecdotally to wood-burning smoke, high rates of naso-pharyngeal colonization with potentially pathogenic bacteria, and inadequate or unavailable health care. Poverty is a major risk factor in developing countries and certain neglected populations⁽⁴⁾. Risk factors associated with acute otitis media may also be initially involved (viral and bacterial infection); eustachian tube dysfunction; young age and immature or impaired immunologic status; upper respiratory allergy; familial predisposition and smoking⁽⁵⁾.

Risk factors that can be targeted should be identified. Overcrowding and exposure to wood and cigarette smoke should be reduced; poor hygiene should be improved, including access to clean water. Health education messages in relation to personal hygiene could be developed to target known risk factors, such as having access to hand washing facilities may reduce spread. In addition to health education for positive practices, negative ones such as instilling various substances in the ear eg oil, milk, leaf extract, cows urine should also be targeted⁽⁶⁾.

The nurse who is a skilled educator should take the lead in improving patients' compliance. The responsibilities of the nurse include ensuring that the patient understands the regimen and arranging needed follow-up⁽⁷⁾.

Aim of the study: assessment risk factors for patient undergoing tympanoplasty.

Significance of the study:

Perforated eardrums results of trauma, such as an object in the ear, hospital statistical record of 2013 –2014⁽⁸⁾ illustrates that approximately 120 cases flow to outpatient clinic and department of Ear Nose and Throat at Aswan university hospital with perforated eardrums related to negligence and poor hygienic. This cause severe complications than, affect the patient hearing. Hence this study will try to assess the risk factors; which may help health professionals specially nurses in planning health education program for this patient.

2. Subjects and Methods**Research design:**

A descriptive exploratory design was utilized to fulfill the aim of this study.

A. Setting:

The study was conducted at the outpatient clinic and department Ear Nose and Throat of Aswan university hospital.

B. Subjects:

Convenience sample of 200 adult patients, with diagnosis of perforated eardrum undergoing tympanoplasty, from both sexes and with different education level, represent the study sample.

Tools:

I. Tool I: Structured interview questions and Medical Data Sheet; this tool was developed by the researcher to assess socio demographic and medical data of the participants. It was comprised of parts:

Part I: socio demographic data as age, sex, level of education; marital and occupational status.

Part II: Patients' medical data as causes of perforation, duration of perforation, ear infection, and post history of otitis media.

Tool II: Risk factors assessment: structure interview schedule:

This tool was developed by the researcher and quoted from risk factors of tympanoplasty (Lasisi, *et al.*, 2007 and Pinar, *et al.*, 2008) and complications of otitis media (Schwaber, 2009) to assess risk factors pertaining to tympanoplasty it was included of two parts as:

Part I: Risk factor: it includes 42 items, history of smoking 3 items, hygienic care 33 items, socioeconomically stat 2 items, and time of ear infection 4 items.

Part II: Patient problems: it consist of 25 items as: ear ache, bleeding from the ear, ear discharge, dizziness, fever, imbalance and vertigo, headaches, tinnitus, hearing loss, and facial nerve weakness. Data obtained analyzed against normal values.

The scoring system of patients' tools:

The possible response of problems (part I, II)

was present and absent. The score of present = "1" means unsatisfactory and absent score = "0" means satisfactory.

The content validity of this tool was checked by expert professors in fields of medicine and nursing and correction was carried out accordingly.

The reliability was 0.9, by the Kuder–Richardson-20 (KR-20) formula. KR-20 is used with dichotomous items.

Ethical Consideration

Written informed consent was taken from each patient after explaining the purpose and benefits of this research. The researcher emphasized that participation in the study was entirely voluntary and each patient has the right to withdraw from the study at any time without giving any reason. As well, anonymity and confidentiality were assured through data collection and coding.

A pilot study

It was carried out on 10% of the study subjects, who were excluded from the main study. The pilot study was done to ensure clarity, applicability, feasibility of the study tools, and time needed for each tool to be filled in. some modifications were done according to the pilot study findings.

Fieldwork:

The purpose of the study was simply explained to patients who agreed to participate in the study prior to any data collection. Data collection extents about 18 months, started from December 2013 until the end of March 2015. The data was collected by the researcher who attended to Aswan university hospital outpatient clinic and department Ear Nose and Throat for two days per week (Monday and Wednesday). The interview method was used to collect the patients date preoperative; to assess the risk factors, using risk factors assessment tools (I and II).

Administrative Design

An official permission to conduct the study was obtained by the researcher from the director of Aswan university hospital. As well from the head nurse of outpatient clinic and department of Ear Nose and Throat, at initial interview.

Statistical Design:

The collected data were coded then transformed into specially designed form so as to be suitable for entering into IBM compatible computer. All entered data were verified for any errors using Statistical Package for Social Sciences (SPSS) version 21 for windows. Descriptive statistics as number, percentage, mean and standard deviation. Data were

collected, tabulated and statistically analyzed using Chi-square test, t-test, and ANOVA test. Test of significance were considered as follows:

No significant (NS) $P > 0.05$

** Significant $P < 0.05$*

*** Moderate significance $P < 0.001$*

**** Highly significance (HS) $p < 0.000$*

3. Results:

Table 1 regarding to socio-demographic characteristics revealed that the age of sample ranged from 20 to greater than 62 years old, with a mean of 43.34 ± 5.56 . 29.5% of studied sample were found in the age group 40 years old. The majority (53.0%) of studied sample were female patients. Approximately 57.0% of studied sample were illiterate. Approximately 92% were unemployed, and 63.5% of studied sample were married

Table 2 shows that, regarding hygienic care, 82.5% were unclean. The majority (75.0%) of the studied sample were of poor socioeconomic status. Approximately 69.5% were otitis media and 41.5% of studied sample are smokers.

Figure 1 depicts that 200 (100%) of patients had vomiting, while 126 (63.0%) complain from nausea. 200 (100%) had fever, 127 (63.5%) complain from tinnitus. While the minority (32.5%) of the studied

sample had changes in taste when eating, the majority (100%) of the patients had hearing impairment, discharge from ear, blurring of vision, migraine and pain of mastication.

Figure 2 illustrates that, about half (53%) of the studied sample were female, while the majority of the studied sample practiced unclean hygienic care (82.5%). More than half (75%, 57%, 69.5%, and 41.5%) of sample considered risk factors as poor of socioeconomic status, illiterate, otitis media, smoking.

Table 3 revealed that there was significant difference between otitis media and smoking ($P < 0.001$) where 80.32% of patients with otitis media were female.

Table 4 illustrate that there was highly significant difference between otitis media and sex ($P < 0.000$) where 80.32% were female.

Table 5 shows that there was highly significant difference between otitis media and socioeconomic status ($P < 0.000$) where 88.52% of patients with otitis media were poor.

Table 6 revealed that there was moderate significant difference between otitis media and hygienic care ($P < 0.001$) where 93.44% of patients with otitis media were unclean.

Table (1): Frequency and percentage distribution of the study sample according to socio demographic characteristic.

Variable	Number of patients (n=200)	Percent
Age group:		
• <20	16	(8.0%)
• 20-	16	(8.0%)
• 30-	22	(11.0%)
• 40-	59	(29.5%)
• 50-	20	(10.0%)
• >60	7	(3.5%)
Mean \pm SD	43.34 \pm 5.56	
Gender:		
• Male	94	(47.0%)
• Female	106	(53.0%)
Educational level:		
• Illiterate	114	(57.0%)
• Preparatory	28	(14.0%)
• Second school	42	(21.0%)
• University	16	(8.0%)
Occupation:		
• Employee	35	(17.5%)
• Unemployed	92	(46.0%)
• Skilled worker	73	(36.5%)
Marital status:		
• Single	45	(22.5%)
• Married	127	(63.5%)
• Widowed	28	(14.0%)

Table (2): Distribution of the study sample related to Risk factors for tympanoplasty.

Variable	Number of Patients (n=200)
Hygienic care:	
• Clean	35 (17.5%)
• Unclean	165 (82.5%)
Socioeconomically status:	
• Poor	150 (75.0%)
• Good	25 (25.0%)
Otitis Media	139 (69.5%)
Smoking	83 (41.5%)

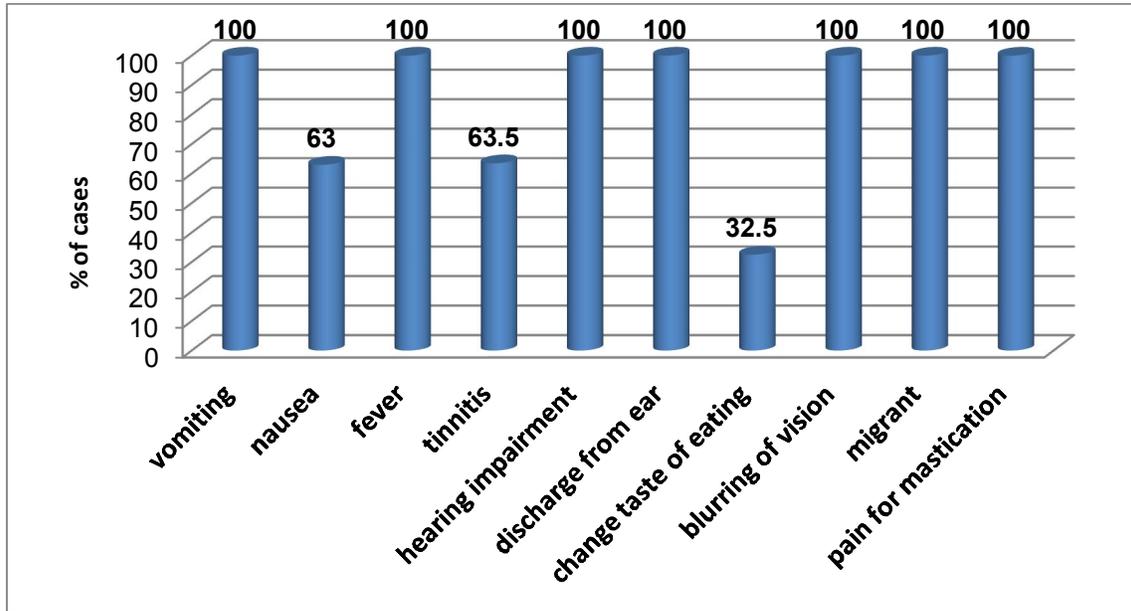


Fig (1): Distribution of the study sample according to clinical manifestation pre tympanoplasty.

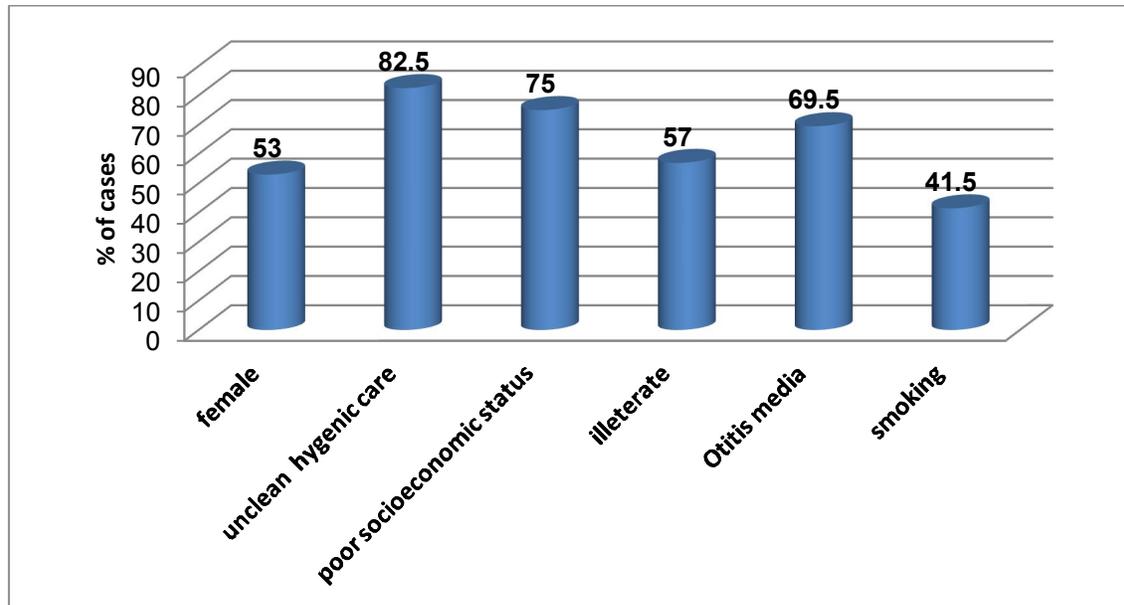


Fig (2): Distribution of patients according to risk factors for tympanoplasty.

Table (3): Distribution of the study sample related to relation between gender and otitis media.

Item	Otitis media "n=139"	No Otitis media "n=61"	p-value
Gender:			
• Male	44(31.65%)	50(81.96%)	P<0.001
• Female	95(68.34%)	11(18.03%)	

Table (4): Distribution of the study sample related to relation between smoking and otitis media.

Item	Otitis media "n=139"	No Otitis media "n=61"	p-value
Smoking:			
• No	62 (44.60%)	55 (90.16%)	P<0.001**
• Yes	77 (55.39%)	6 (9.83%)	

Table (5): Distribution of the study sample related to relation between socioeconomic status and otitis media.

Item	Otitis media "n=139"	No Otitis media "n=61"	p-value
Socioeconomic status:			
• Poor	129 (92.81%)	46 (75.40%)	P<0.000***
• Good	10 (7.19%)	15 (24.59%)	

Table (6): Distribution of the study sample related to relation between Hygienic care and otitis media.

Item	Otitis media "n=139"	No Otitis media "n=61"	p-value
Hygienic care:			
• Clean	9(6.47%)	26(42.62%)	P<0.001**
• Unclean	130(93.52%)	35(57.37%)	

4. Discussion:

Tempanoplasty is the operation specifically designed to close tympanic membrane defects. A perforation in the tympanic membrane can result from physical injury, scalds, burns, pressure effects, head injuries or infection process; out of this suppurative process is the most common cause. Factors affecting the success rate of surgery and healing process as infection and certain pathophysiological changes at the perforated margin, leading to a non-healing, permanent perforation. It leads to constant exposure of middle ear for reinfection hearing disability and danger of certain intracranial and extracranial complications^(12, 13, & 14).

The age of sample of the presented study ranged from 20 to 62 years old; the majority of the age group of the studied sample ranged between 30 to 40 years old. A study conducted by Ajmhal⁽¹⁵⁾ agree with the presented study and found that 66% of the patients belonged to the age group of more than 35yrs and 33% of them belonged to less than 35 years.

In the presented study, approximately 25% of the sample were under 20 years old, more than a quarter of the study between 21-45 years old, and more than half of the study sample above the age group of 45 years. Hence it seems to be better when the surgery is performed in the middle age groups. Lasisset *et al.* (2007) found the results of ear surgery in young age to be less successful than in adult patients.

The majority of presented studied sample were female patients. In a ten years retrospective study by

Mustafa *et al.*⁽¹⁶⁾ on complications of otitis media with tympanoplasty, there were 55 (60.4%) and 36 (39.6%) were women, and the difference was statistically significant. Another study by Gandhi *et al.*⁽¹⁷⁾ from India in their study showed that male to female ratio was 2.1:1. Yogancilar *et al.*⁽¹⁸⁾ in his study showed a male to female ratio of 1.16:1. Only one study, by Westerberg *et al.*⁽¹³⁾ from India showed that females were more prone for complications (M: F=1:1.10). In the series by Osmaet *et al.*⁽¹⁹⁾ the authors found a significant difference in the men-to-women ratio of 2:1.

Retrospective study by DubeyLarawin⁽²⁰⁾, male to female ratio was 3:1. In the present study out of 72 patients 49 (68.05%) were male and 23 (31.94%) were female. The male to female ratio was 2.1:1.

In present study there were a significance difference between gender and otitis media. The majority of studied sample were female. The results explain relation between the genders and otitis media. The difficulty in maintaining long hair in females may be a reason for the graft infection since most of them experiences difficulty in keeping their hair clean during the postoperative period. But Karelaet *al.*,⁽²¹⁾ in their study did not find any difference in success rates among the gender.

In a report published by Yorgancilaret *al.*⁽¹⁸⁾ from Turkey, majority of the patients were in the age group 21-30 years whereas a study by Gandhi *et al.*⁽¹⁷⁾ from India showed that majority of patient (67.8%) were under the age of 15. In a study by Dubey⁽²⁰⁾ in 2007, 22 (31%) patients were in the first

decade, 17(24%) patients were in the second, 21 (30%) in the third, 5 (7%) in the fourth, 2(2.9%) in the fifth and one each in sixth, seventh and eighth decade. In the present study there were 36 (50%) patients in the age group 1-20 years. Further analysis showed that the large number of complications Osma⁽¹⁹⁾ occurred in the age group of 15 to 20 yrs. There is a shift in the higher incidence of tympanoplasty complications associated with chronic suppurative otitis media from pediatric to young adolescent age group.

Mustafa *et al.*⁽¹⁶⁾ did not find significant difference among patients in clean and unclean areas. In this respect, Osma *et al.*⁽¹⁹⁾ found that the complications were more common in unclean patients than in urban patients. In study by Vakinpelu *et al.*⁽²²⁾ from Nigeria, most patients were from unclean areas and had been previously managed by unlicensed, untrained practitioners. Complications were mostly present in children.

In the present study quarter of the study sample was clean hygienic care and more than half of the study sample was unclean hygienic care. The probable reason why these complications are still encountered more in the unclean may be due to decreased awareness and ignorance towards the seriousness of persistent and sometimes offensive ear discharge. This agree with Shaheen *et al.*⁽²³⁾ revealed statistically significant association of chronic otitis media with yearly income of guardian, maternal education, bathing habit, ear cleaning habit, pattern of primary medical consultation.

In the present study complications were seen more in the literate patients (55.55%) as compared to illiterate patients (44.45%), which may be attributed to the shift in literacy patterns in the country. Mustafa *et al.*⁽¹⁶⁾ found that complications were seen more in young patients from a lower socioeconomic class and without sex preponderance. In this respect, Lasisi *et al.*⁽⁹⁾ were of the opinion that low socioeconomic class, malnutrition, congestion from high number of people significant risk factor. In the present study more than half patients of the studied sample were low socioeconomic group with bad health habits and half of the studied sample patients were from high socio economic group.

In the study conducted by Schwaber *et al.*⁽¹¹⁾ Chinese sample have been reported to have a lower prevalence rate (1.3%) than Caucasian (9.5%). While study by Jaarsma⁽²⁴⁾ showed lower prevalence in lower socio economic status, in our study we found out that there was higher prevalence of Otitis media of effusion among students belonging to lower socio economic status.

The reasons for the higher number in lower socioeconomic status might be the poor hygienic

standards in this population, overcrowding in these families and most importantly poor nutritional status this considered risk factors for tympanoplasty failure. In addition to the impairment of physical growth and of cognitive and other physiologic functions, malnutrition also has effect on immune response changes like loss of delayed hypersensitivity, fewer T lymphocytes, impaired lymphocyte response, impaired phagocytosis secondary to decreased complement and certain cytokines.

Thus Malnutrition predisposes to infection and infection to malnutrition. Hence lower socio economic status is susceptible for malnutrition and thus a higher chance of getting OME.

In present study there were more than half complain of tinnitus and 100% have fever this comparing with Dubey *et al.*⁽²⁰⁾ the commonest symptoms were tinnitus in 63 (90%) patients; fever in 97 (98%). The most frequent symptoms in Yorgancilar's⁽¹⁸⁾ study was otorrhea, headache and fever. Study by Pendio *et al.*⁽²⁵⁾ showed that persistent fever, headache, and purulent otorrhea were the main symptoms. Kangasanarak⁽²⁶⁾ stated that purulent malodorous tinnitis, headache fever and nausea and vomiting were the significant alarming manifestations.

According to Huseyin⁽²⁷⁾, 93% patients had headache, 87% fever, and 62% altered mental status. There were the most common presenting symptoms and signs, along with symptoms of chronic otitis media. In study of early neurotologic clinical features of otitis media, Schwaber *et al.*⁽¹¹⁾ are of the opinion that purulent, malodorous discharge, headache and fever are the significant early signs and symptoms that should raise the index of suspicion. Altered mental status is a late finding and usually indicates established intracranial spread of infection. In the present study otorrhea, Headache and fever the commonest symptoms associated with complications. Other symptoms were otalgia giddiness and vomiting.

In addition, Yorgancilar *et al.*⁽¹⁸⁾ reported 12 patients with sensor neural hearing loss. Osma *et al.*⁽¹⁹⁾ in his study observed five cases with profound deafness of which two were associated with extra cranial and other three with intracranial complications. They had five patients with profound hearing loss in the study group of 93 patients.

In this respect, Leskinen and Jero⁽²⁸⁾ reported permanent hearing loss in 13 (26%) patients. Moreover, Kasliwal *et al.*⁽²⁹⁾ suggested that more severe middle ear disease may result in sensor ineural hearing loss and they suggested early intervention in cases of chronic suppurative otitis media. Kolo *et al.*⁽³⁰⁾ found that patients with chronic suppurative otitis media had a significant degree of sensor ineural

hearing loss. The higher frequencies were more affected. Patient's age and duration of otorrhea seem not to have any correlation with the degree of sensorineural hearing loss.

Moreover, Blakley. And Jero⁽³¹⁾ showed a highly significant association between the presence of chronic otitis media and sensorineural hearing loss. In a series by Kaur *et al.*⁽³²⁾ the incidence of sensorineural hearing loss was 24% and particularly it was seen in higher frequencies. Authors also found that the incidence of sensorineural hearing loss progressively increased with the duration of chronic suppurative otitis media.

In present study there were significance difference between otitis media and smoking were ($P < 0.001$) where more than half of patients with otitis media were female. Furthermore, several risk factors may account for the increased rate of bacterial colonization associated with exposure to tobacco smoke. Cigarette smoke decreases mucociliary clearance by respiratory epithelium, potentially facilitating bacterial colonization Wanner⁽³³⁾ and Stanley *et al.*⁽³⁴⁾. In support to the first explanation, several research groups have demonstrated increased adherence of bacteria to respiratory epithelial cells of smokers, compared with nonsmokers (El Ahmer *et al.*⁽³⁵⁾ and Fainstein and Musher⁽³⁶⁾). Finally, tobacco smoke induces inflammation, which may result in epithelial injury, predisposing to bacterial colonization become major risk factors (Willemse *et al.*⁽³⁷⁾).

Perforated eardrums with negligence and poor hygienic care considered risk factors for ear infection and graft failure. This cause severe complications than, affect the patient hearing. Smoking and poor socioeconomic status caused risk factors for tympanoplasty undergoing surgery. Hence this study will try to assess the risk factors; which may help health professionals specially nurses in planning health education program for these patients.

Conclusions:

Factors indicating significant were, middle age group, female gender, and low level of educational, regarding hygienic care wear bad habits, passive smoking and poor socioeconomic status.

Recommendation

Establishing health educational program for patients with tympanoplasty to improved patients outcome.

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