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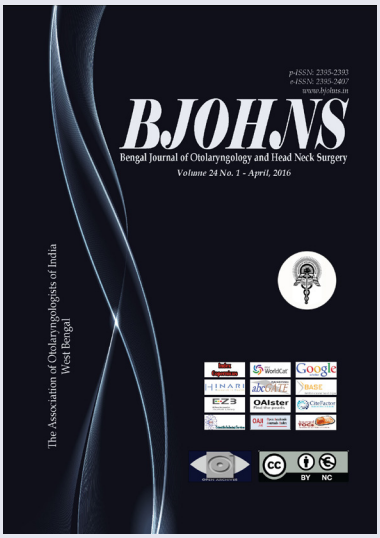

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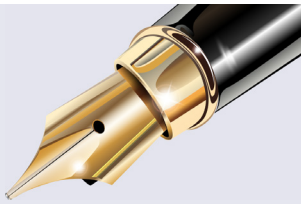
From the Desk of the Editor



During the last few decades, the traditional healing art of medicine has been transformed into a business entity. The transformation of the modest medical centres run by doctors into sprawling medical industrial complexes managed by corporate HMO (Health Maintenance Organizations) had active encouragement of the Government, media and the public in general. The rise of corporate health care has been coupled with decline of the Government hospitals, mainly due to Governments' reluctance to increase budgetary allocation to shoulder the increased health care expenditure which was needed to keep pace with the modern scientific developments.

Promotions and advertisements came in a big way. The scientific medicine, powered with the cutting edge technology, has been projected to have the potential to cure all ailments. Society places a much higher premium on using technology than on listening or counselling. Treatment protocols were formulated on scientific data; communicating with an ailing person was discounted. Doctors had been projected to be highly skilled scientists with the ability to salvage every situation. The cost of treatment in a scientific curative medical centre may be astronomical but people knew that every good thing comes at a cost. A dream has been sold and 'the public was led to expect miracles and these were not forthcoming. The result is disillusion and anger'.

The members of the society must appreciate that they themselves subscribed to the belief that investor-owned health maintenance organizations were the only option to improve the quality of health care delivery. The health industrialists entered on the invitation of the Society, started employing the doctors as mere employees of the health industry and marketised their product professionally. The society supported the business model of health system. It is again the Society, which believed that bracketing the doctors with the businessmen by placing them under the purview of the Consumer Protection Act, would force them to perform better. Now the Society screams that too much business has been done.

It is time for the Society to introspect and choose if it wants to run the healthcare sector as an essential public service or it wants the healthcare industry to take charge. It cannot have its feet on two boats and hope to cross the river. It is for the Society to decide if doctors should be allowed to be guided by the Hippocratic Oath or should they be governed by corporate philosophy. The Society would get the healthcare it deserves.

Dr Saumendra Nath Bandyopadhyay
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Comparative Study of Autologous Ossicular Graft versus Titanium Prosthesis (TORP & PORP) in Ossiculoplasty

P Thamizharasan,[1] K Ravi[1]

ABSTRACT

Introduction

This prospective cohort study aims to analyze and compare the outcomes of ossiculoplasty in terms of hearing results, intra and post operative course, using autograft incus and titanium middle ear prosthesis.

Materials and Methods

Patients with a history of chronic ear discharge and conductive deafness were included in the study. Out of 21 patients with ossicular chain defect included in the study, 10 patients underwent ossiculoplasty with autograft incus and 11 with titanium prosthesis. Pure tone audiogram was done after three months.

Results

In patients with incus ossiculoplasty, average Post operative PTA was 43.5 dB ± 7.934SD and Net gain in hearing was 10.7 decibels ± 15.478SD. In patients with titanium prosthesis ossiculoplasty, average Post operative PTA was 41.4 dB ± 4.789SD and Net gain in hearing was 16 decibels ± 11.981SD.

Discussion

Three patients underwent only Tympanoplasty post operative PTA was 42 ± 5.292 dB (incus- 39 dB, titanium- 48dB) and hearing gain was 13.33 ± 12.583 (incus-20dB, titanium-0dB). Five patients underwent intact canal wall with Tympanoplasty: Post operative PTA was 35 ± 3 dB (incus-35dB, titanium-30dB) and hearing gain was 23 ± 15.379 (incus-18.33dB, titanium-30dB). Thirteen patients underwent canal wall down procedure with Tympanoplasty: Post operative PTA was 45.67 ± 5.228 dB (incus-50.4dB, titanium-41.8dB) and hearing gain was 9.33 ± 12.309 (incus-2.4dB, titanium-14.285dB). Complications in the short period studied were nil in both groups.

Conclusion

Incus and titanium have equal postoperative hearing but in terms of hearing gain Titanium prosthesis gave a better hearing gain than incus.

Keywords

Ossicular Prosthesis; Incus; Titanium

Hearing is one of the most important special senses of human being. A good hearing is important for acquiring knowledge and improved productivity of human beings. A person with hearing impairment has decreased privilege of enjoying the aesthetics of life and has difficulty in carrying out his day to day activities. Reports of NSSO survey in the year 2001 suggest that there are 291 persons per one lakh population suffering from severe to profound hearing loss.[1] The incidence of chronic otitis media is high in India, and ossicular chain destruction or erosion is a common complication of chronic suppurative otitis media.

Ossiculoplasty is done using either biological or alloplastic materials.[2] Autograft or homograft ossicles, bone and cartilage are the biological materials used in reconstruction of ossicles. Autologous ossicles are

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the most preferred materials for reconstruction. The advantages with autologous ossicles are low extrusion rate, low cost, biocompatibility and no risk of disease transmission. However, the disadvantages are that they are not always available in chronically infected ears and in cases with cholesteatoma; ossicles with microsquamous deposits may lead to residual disease. The prolonged operative time to sculpt and shape, resorption or loss of rigidity of the reconstructed ossicles, possible fixation to the walls of middle ear and persistent osteitis in the ossicles are other disadvantages with autologous ossicles.

Nowadays alloplastic materials are commonly used for ossiculoplasty. They are classified as Biocompatible, Bioinert and Bioactive. Of all alloplastic materials, Titanium is an excellent biocompatible material; it is light but strong, and allows for many different prosthetic designs.[2] It has good long term success rates. Titanium forms a biostable titanium oxide layer when combined with oxygen.[2] Titanium has shown significant biostability in the middle ear for the past 10 years. It has low ferromagnetism. Moreover titanium is lightweight and rigid, making it a good sound conductor. The advantages are - it is available pre-sculptured with every type and design, surgery time is reduced and there is no risk of any residual or transmitted disease. However the disadvantages of titanium are cost, ossicular necrosis, extrusion, displacement and unsatisfactory hearing restoration.

There are not many studies which have proved the efficacy of these materials in terms of hearing results. In our study, we have subjected the patients with ossicular erosion to ossiculoplasty using autologous ossicular graft versus titanium prosthesis (TORP- total ossicular replacement prosthesis and PORP- partial ossicular replacement prosthesis) and compared the efficacy in terms of operative course, post operative sequelae, complications, anatomical and functional results.

Materials and Methods

The study population consisted of patients who attended the Ear, Nose and Throat (ENT) outpatient department at our hospital from December 2014 to December 2015. The study design was Prospective cohort study of patients undergoing ossiculoplasty in our hospital. Patients between 12-60 years of age suffering from chronic otitis media with ossicular erosion or ossicular discontinuity following trauma were included. Patients with eustachian tube dysfunction(viz. cleft palate patients), sensorineural and mixed hearing loss, medically unfit, having coexisting facial nerve palsy and labrynthitis, adhesive otitis media, active discharge inspite of culture specific antibiotics and disease over foot plate of stapes not amenable to complete removal were excluded.

Preoperatively patients underwent pure tone audiometry. The degree of hearing loss is assessed by taking pure tone average of hearing intensities in decibels at frequencies of 500, 1000, and 2000 Hertz. Computed tomography was done in all cases to assess the extent of middle ear pathology (cholesteatoma), ossicular chain abnormalities and inner ear anatomy.

After these investigations all patients were operated under general anesthesia after obtaining informed consent for participating in our study. During surgery the extent of disease and availability of disease free ossicles according to Austin classification[3] were analysed (M = Malleus, S = stapes, + = present, - = absent).

After ensuring complete disease clearance, ossiculoplasty was done in the primary sitting itself. Autologous ossicular graft, autologous incus, if available was the first choice always. The height of incus was assessed if it was adequate from the foot plate or suprastructure to the tympanic membrane. The incus was held with ossicle holding forceps with reshaped with diamond burr creating a facet for suprastructure of stapes or flattened edge for footplate of stapes (Fig.1) and tympanic membrane or graft placed. The time taken for ossiculoplasty is noted and recorded.

If incus was not available or height of incus was inadequate, then titanium Total or Partial Ossicular Replacement Prosthesis (TORP or PORP) was used depending on the presence or absence of suprastructure of stapes. The prosthesis was measured for distance between tympanic membrane and footplate or suprastructure of stapes (Fig.2). The ossiculoplasty is done with a cartilage cap over the prosthesis as interface between prosthesis and tympanic membrane.

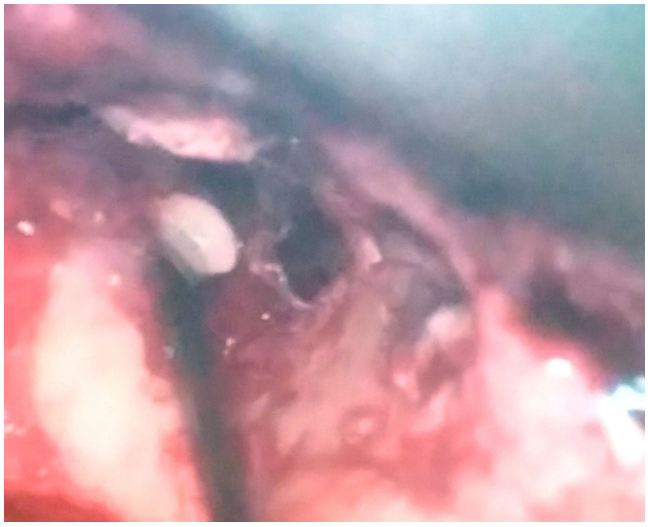

Fig.1. Incus placed over footplate of stapes

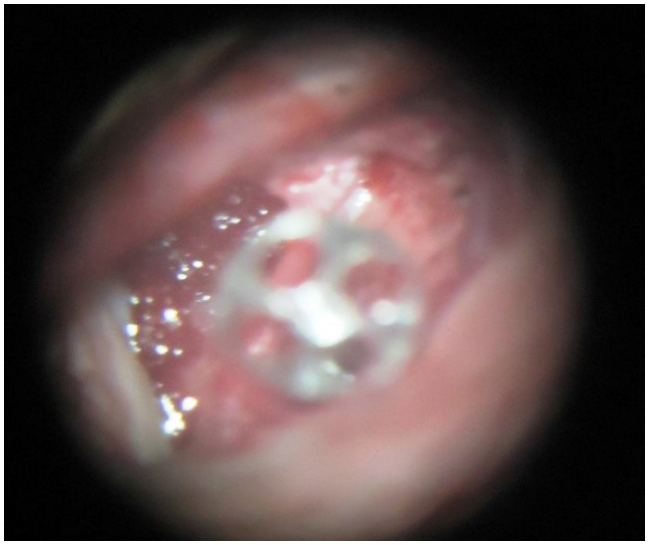

Fig.2. Titanium TORP over footplate of stapes

In intact canal wall mastoidectomies, tragal cartilage was harvested and in canal wall down mastoidectomies, conchal cartilage removed during meatoplasty was used. The duration taken for ossicular reconstruction was noted.

Patient was followed up with otoscopic examination every week during the first month and monthly for next 3 months. Pure tone audiometry was performed after 3 months.

Results

Among 21 patients (Table I) who underwent ossiculoplasty, 10 patients were operated with incus transposition and 11 patients with titanium. Among titanium implantees, 7 patients received TORP (Total Ossicular Replacement Prosthesis) and 4 patients received PORP (Partial Ossicular Replacement Prosthesis).

The age of patients in this study were between 14-56 years of age. There were 12 male patients and 9 female patients. 8 patients were less than 18 years of age (in whom consent was obtained from parents), 5 patients between 19-30 years, 4 patients between 31-40 years of age and 4 patients above 40 years of age.

In patients with incus ossiculoplasty, average post operative pure tone hearing level (HL) was 43.5 dB (SD 7.934) and net gain in hearing was 10.7 decibels (SD 15.478).

In patients with titanium prosthesis ossiculoplasty, average post operative pure tone HL was 41.4 dB (SD 4.789) and net gain in hearing was 16 decibels (SD 11.981). The average postoperative hearing after ossiculoplasty is 43.5 dB.

Discussion

In patients with tympanoplasty, incus was used in 2 cases. Hearing gain was 25 dB for ossicular discontinuity due to trauma and hearing gain was 15 dB for revision case. Titanium was used in 1 case of revision tympanoplasty which had no net gain. The post op PTA including both groups was 42 ± 5.292 dB (incus- 39 dB, titanium- 48dB) (p =0.002) and hearing gain was 13.33 ± 12.583(incus-20dB, titanium-0dB) (p=0.178).

In patients with intact canal wall mastoidectomy, Incus was used in 3 cases. All were cases of cholesteatoma. In one case suprastructure of stapes was absent and incus was placed over foot plate; the patient had a post operative hearing gain of 40 decibels. Two cases had intact suprastructure; incus repositioned over it and one had only 2 decibel hearing gain and another had 13 decibels hearing gain. Titanium was used in 2 cases. Both patients had retraction pockets without cholesteatoma.

Titanium TORP was used in one case and had a gain of 33 decibels, Titanium PORP was used in one case and had a gain of 27 decibels. The postoperative PTA including both groups was 35 ± 3 dB (incus-35dB, titanium-30dB) (p =0.002) and hearing gain was 23 ± 15.379 (incus-18.33dB, titanium-30dB) (p=0.178).

In patients with canal wall down mastoidectomy, incus was used in 5 cases. All cases had cholesteatoma with absent suprastructure of stapes. Postoperatively one case had worsened hearing loss of 12 dB and another case had hearing loss of 10 dB. Both cases probably had bridging cholesteatoma in the place of eroded ossicles and the reconstructed incus could not transmit sound as like them. The other cases had hearing gain of 17 dB, 9 dB and 8 dB. Titanium PORP was used in 3 cases ; one case had hearing loss of 3 dB and other two had hearing gain of 7 dB and 24 dB. Titanium TORP was used in 5 cases. Suprastructure of stapes was absent in all cases. They had hearing gain of 12 dB, 16 dB, 18 dB, 26 dB and one case was lost to follow up. The post op PTA including both groups was 45.67 ± 5.228 dB (incus-50.4 dB, titanium-41.8 dB) (p =0.002) and hearing gain was 9.33 ± 12.309 (incus-2.4dB, titanium-14.285dB) (p=0.178).

Zakzouk et al, in 2015, had 49 total ossicular reconstructions (titanium prosthesis, 40 patients; autologous incus, 9 patients) and mean air-bone gap at 2 years after surgery for the titanium prosthesis (21 dB) and autologous incus group (31 dB; $P \leq 0.03$).[4] Amith et al, in 2011, had done a similar study and mean preoperative

Table I : List of patients who had undergone ossiculoplasty

S. NO.	AGE / SEX	DIAGNOSIS	PROCEDURE DONE	OSSICULAR STATUS	INCUS / TITANIUM	PRE OP PTA	POST OP PTA	HEARING GAIN
Tympanoplasty alone								
1.	48/F	Left traumatic ossicular discontinuity	Left tympanoplasty	M+ S+	Incus	65 dB	40 dB	+ 25dB
2.	33/F	Left CSOM with dry central perforation	Left tympanoplasty	M+ S+	Incus	53 dB	38 dB	+15 dB
3.	43/F	Right post MRM residual perforation	Right revision tympanoplasty	M- S-	TORP	48 dB	48 dB	Nil
Intact canal wall mastoidectomy with Tympanoplasty								
4.	25/F	Left PSRP with cholesteatoma	Left Intact canal wall	M+ S+	Incus	40 dB	38 dB	+2 dB
5.	18/F	Right PSRP with cholesteatoma	Right Intact canal wall	M+ S+	Incus	45 dB	32 dB	+13 dB
6.	27/M	Right CSOM with extensive granulation	Right Intact canal wall	M+ S-	Incus	75 dB	35 dB	+ 40dB

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7.	13/M	Left CSOM with PSRP	Left Intact canal wall	M+ S-	PORP	65 dB	38 dB	+27 dB
8.	18/F	B/L CSOM with PSRP	Right Intact canal wall	M+ S-	TORP	65 dB	32 dB	+ 33dB
Canal wall down mastoidectomy with Tympanoplasty								
9.	18/M	Right PSRP with cholesteatoma	Right CWD	M+ S-	Incus	36 dB	48 dB	- 12 dB
10.	41/M	Right PSRP with cholesteatoma	Right CWD	M+ S-	Incus	42 dB	52 dB	-10 dB
11.	35/M	Left attic cholesteatoma	Left CWD	M- S-	Incus	56 dB	48 dB	+ 8 dB
12.	56/F	Right cholesteatoma with auto cavity	Right CWD	M+ S-	Incus	65 dB	48 dB	+17 dB
13.	35/M	Left attic cholesteatoma	Left CWD	M- S-	Incus	65 dB	56 dB	+9 dB
14.	27/M	Right attic cholesteatoma	Right CWD	M- S+	PORP	42 dB	45 dB	- 3 dB
15.	17/M	B/L attic cholesteatoma	Right CWD	M- S-	TORP	68 dB	42 dB	+26 dB
16.	29/M	Left attic cholesteatoma	Left CWD	M- S-	PORP	60 dB	36 dB	+ 24dB
17.	23/M	Right attic cholesteatoma	Right CWD	M- S+	PORP	52 dB	42 dB	+ 7 dB
18.	15/F	Right CSOM with extensive granulation	Right CWD	M- S-	TORP	56 dB	44 dB	+ 12dB
19.	36/F	B/L attic cholesteatoma	Left CWD	M- S-	TORP	58 dB	42 dB	+16 dB
20.	14/M	Right cholesteatoma with auto cavity	Right CWD	M- S-	TORP	63 dB	45 dB	+18 dB
21.	15/M	Right attic cholesteatoma	Right CWD	M- S-	TORP	72 dB	Lost followup	

M – MALLEUS S – STAPES
+ - PRESENT - - ABSENT
CSOM – chronic suppurative otitis media,
PSRP- posterosuperior retraction pocket
CWD – canal wall down

AB gap values in autoincus, titanium TORP and PORP groups were 43.3 dB (SD 8.34), 44.2 dB (SD 10.17) and 42 dB (SD 5.7), respectively, whereas the postoperative AB gap closure values were 24.5 (SD 9.15), 30.7 (SD 15.66) and 25 dB (SD 6.12), respectively.[5] There was a statistically significant improvement in pre operative PTA AB gap of 43.3 dB ± 8.34 SD to mean postoperative AB gap of 24.5 dB ± 9.16 SD (P = 0.046) in autologous incus group. Woods et al, in 2008, compared incus reconstruction with the titanium prosthesis groups and found both groups yielded similar outcomes.[6] Maunsell et al, in 2005, did a retrospective study of 98 patient

Table II : Statistical Analysis

VARIABLES	GROUP	N	MEAN	STD. DEV	P-VALUE
Age	Incus	10	33.60	12.349	0.038
	TORP/PORP	11	22.73	9.951	
Pre op PTA	Incus	10	54.20	13.139	0.337
	TORP/PORP	11	59.00	8.989	
Post op PTA	Incus	10	43.50	7.934	0.483
	TORP/PORP	10	41.40	4.789	
Hearing gain	Incus	10	10.70	15.478	0.403
	TORP/PORP	10	16.00	11.981	
Percentage change	Incus	10	15.11	26.79	0.303
	TORP/PORP	10	26.02	18.41	

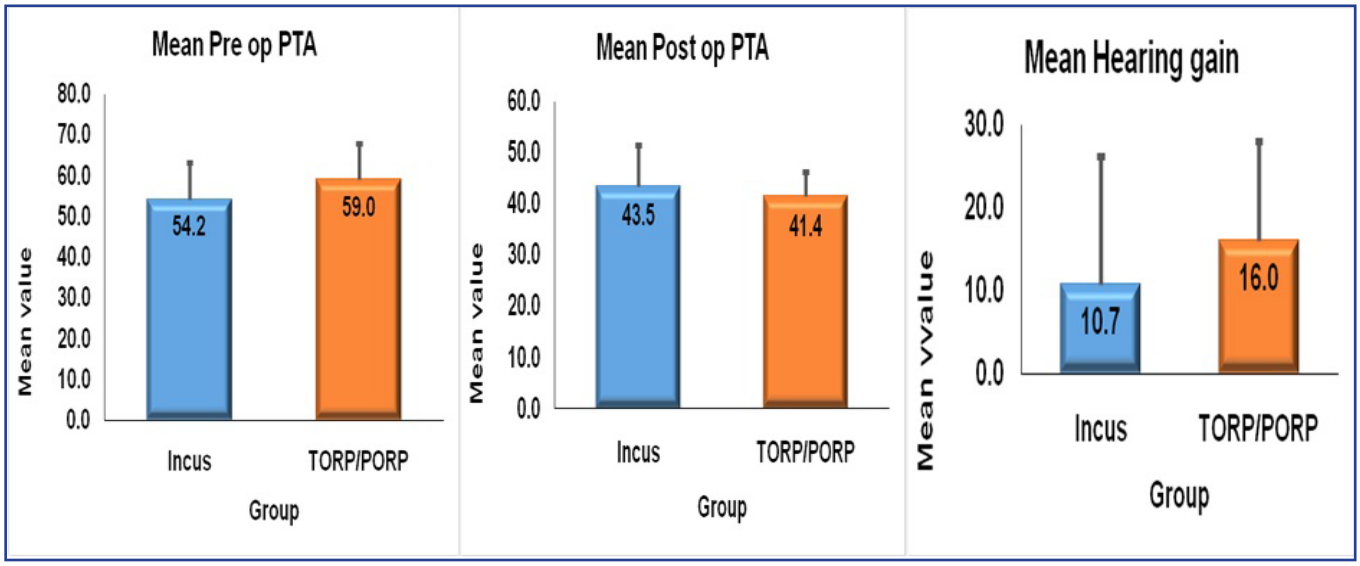

Fig.3. Overall average results between the two groups

having type 2 with the incus and 50 patients received PORP titanium. Postoperative air bone gap was 16.9 dB in the titanium group and 25.5 dB in incus group. Gain was 18.7 dB in incus and 4.3 dB in titanium.[7]

In our series the post operative pure tone average at 3 months is 43.5 dB ± SD 7.934 for incus and 41.4 dB ± SD 4.789 for titanium (p = 0.483). In terms of hearing gain, incus-10.7, titanium-16 (p 0.403).

Zakzouk et al concluded that Titanium prosthesis ossiculoplasty gave better results than autologous incus in the absence of the stapes suprastructure and presence of a mobile footplate.[4]

Postoperative complications in Amith et al[5] with autologous incus group were 25% as compared with titanium prosthesis in which the complication rate was 41.6% and in Maunsell et al[7] rate of extrusion was 1% for incus and 4% for PORP. Other complications such as facial palsy, graft extrusion with residual perforation, severe sensory neural hearing loss, perilymph fistula and atelectasis noted in other studies were nil in our series. In the three month period there were no signs of extrusion in any of the cases. May be a longer follow up period or a challenge of ear discharge without the prescribed ear drops coverage might be needed to declare that there is no extrusion in all the cases. There was no giddiness or tinnitus in any patient. This may be due to the proper case selection with appropriate indications.

Time taken for ossiculoplasty for both incus and titanium prosthesis were almost same and had variations according to individual cases. Incus had to be reshaped, made disease free, and of adequate length to fit in. Similarly titanium prosthesis which we used in all cases has also to be altered in length and cartilage has to be harvested separately if not while meatoplasty and the time taken is considerable. In the postoperative period minor complaints such as cavity problems, otomycosis, within the three month period were equal in both cases and was independent of type of ossicular reconstruction done.

Conclusion

Ossiculoplasty definitely gives better hearing in comparison to cases where ossiculoplasty is not done. Ossiculoplasty should be done in all cases with conductive hearing loss secondary to Ossicular pathology either at primary sitting or second sitting. Incus and titanium has equal postoperative hearing (incus-43.5 dB ± 7.934, titanium- 41.4 dB ± 4.789) (p 0.483). In terms of hearing gain Titanium prosthesis gave a better hearing gain than Ossicular transposition (incus-10.7, titanium-16) (p 0.403). Autologous ossicles are not available in the desired length in all cases. Cost of titanium is a concern. Long term results are awaited. Our case series is not big enough and the period of study is one year and data after three month period follow up is not included in the study which may be suggested as pitfalls in our study.

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The Incidence of Thyroid Cancer in England and Wales over A Ten Year Period

Louise Marie Evans,[1] Michael Stechman,[2] David Owens[2]

ABSTRACT

Introduction

The incidence of thyroid cancer has increased worldwide, whether a real or apparent increase is debated. Literature from the USA suggests greater diagnostic scrutiny, environmental and genetic factors may all play a part. This increase will result in a greater number of referrals for surgical assessment. This study examined the trend in incidence of thyroid cancer in England and Wales.

Materials and Methods

A retrospective study, using the HES database over the period 2000-2010. Data were extracted of all newly diagnosed thyroid cancers in England and Wales and the age at diagnosis. Data were examined for the change in incidence of thyroid cancer diagnosis dependent on the age group of the patient using the linear regression model.

Results

45411 patients were identified. In England the incidence of thyroid cancer rose from 5.7/100,000 of the population in 2000 to 9.9/100,000 in 2010 and in Wales it rose from 3.5/100,000 in 2000 to 7.5/100,000. There was a statistical increase ($P \leq 0.02$) (t-stat >2) in the diagnosis of thyroid cancers across all age groups with exception of the 0-14 age group ($P > 0.5$).

Conclusion

There has been a statistical increase in the incidence of thyroid cancer. This is likely to impact on hospitals and cancer service resources. An increase in surgical demand and the coinciding ageing population highlights the importance of further investigation into the etiology, use of imaging, patient demographics, histology and overall mortality of this patient group.

Keywords

Thyroid Neoplasms; Incidence; England; Wales

The incidence in thyroid cancer has increased worldwide, with countries such as Scotland,[1] the USA[2] and Mexico[3] all reporting an increase. Whether this is a true or apparent increase is debated.

The effect of radiation from atmospheric testing of nuclear weapons in the 1950-60s and female reproductive patterns have been considered causative factors for the rise.[4,5,6] The more favored view however is that improvements in technology, more sophisticated imaging techniques and a greater accessibility to ultrasound scanning has resulted in diagnosis of thyroid cancers which may have otherwise gone unnoticed.

There has been little written about the impact of this increase on the patients, the doctors' workload and the health service as a whole. With this in mind we investigated the trends in the incidence of thyroid cancer in England and Wales over a 10-year period.

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Materials and Methods

A retrospective analysis of Health Solutions Wales (PEDW) and the English Hospital Episode Statistics (HES) annual data was conducted over a ten-year period, from the year 2000 to 2010. The numbers of patients who were newly diagnosed with thyroid cancers in England

and Wales adjusted for 100,000 of population each year were examined. The incidence of thyroid cancer rates within four different age groups, 0-15, 16-59, 60-74 and ≥75 years for both England and Wales were analysed. Statistical analysis for change over time was examined using a linear regression model (Microsoft Excel, Microsoft, USA). $P<0.05$ was accepted as statistically significant.

Results

Between 2000 and 2010, 45411 patients were newly diagnosed with thyroid cancer in England and Wales representing 0.08% of the population. Thyroid cancer was found to be most common in the ≥ 60 age group.

Overall, in England, the incidence of thyroid cancer increased significantly from 5.7/100,000 of population in 2000 to 9.9/100,000 of population in 2010. In Wales the incidence rose from 3.5/100,000 in 2000 to 7.5/100,000 (Fig. 1).

The incidence of thyroid cancer in the 4 age-bands collated by HES and PEDW exhibited some variation. In patients aged 0-14 years, there was no significant change over time and the incidence remained between 0 and 0.1 per 100,000 of population over the study period (P=0.6). In all other age groups (15-59 years, 60-74 years, and 75 years and above) there was a significant increase ($P\leq0.02$) (t-stat >2) in the incidence of thyroid cancer from 2000 to 2010.

The changes in incidence over time are shown in figures 2, 3 and 4.

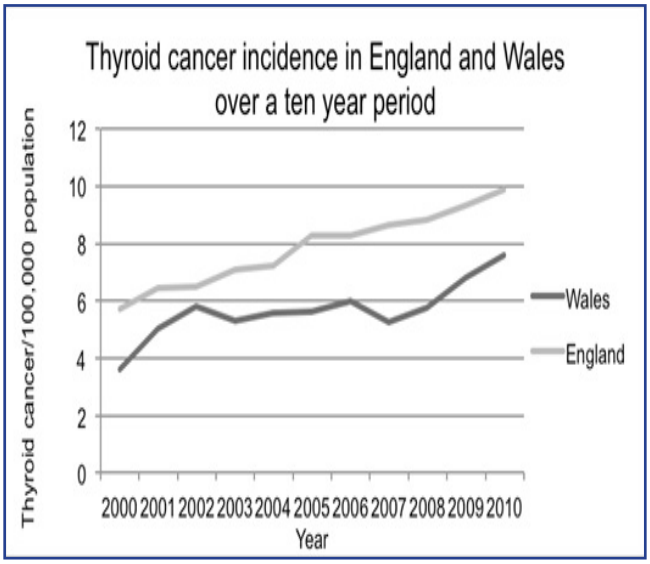

Fig.1. Incidence of Thyroid Cancer

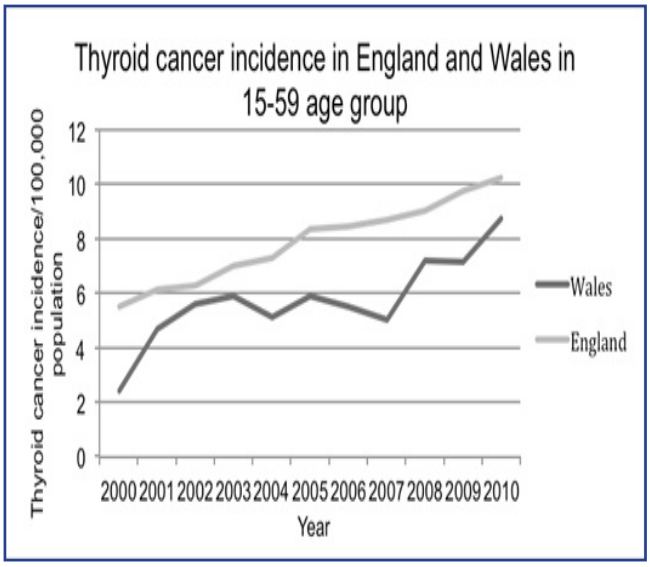

Fig.2. Incidence of Thyroid Cancer in 15-59 years age group

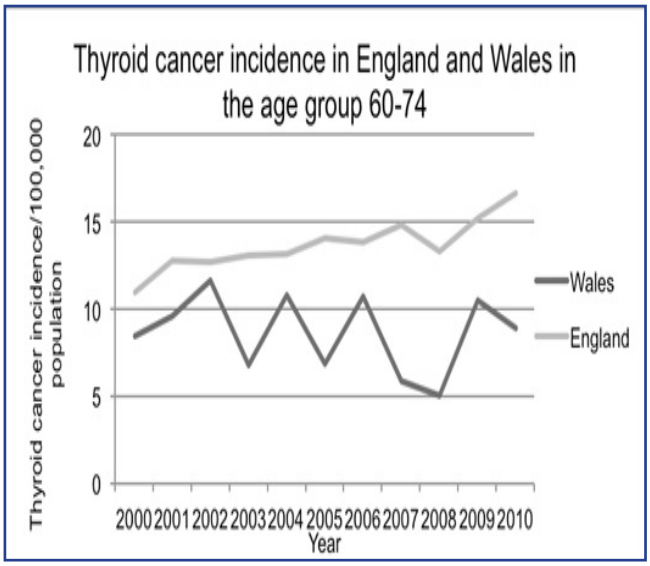

Fig.3. Incidence of Thyroid Cancer in 60-74 years age group

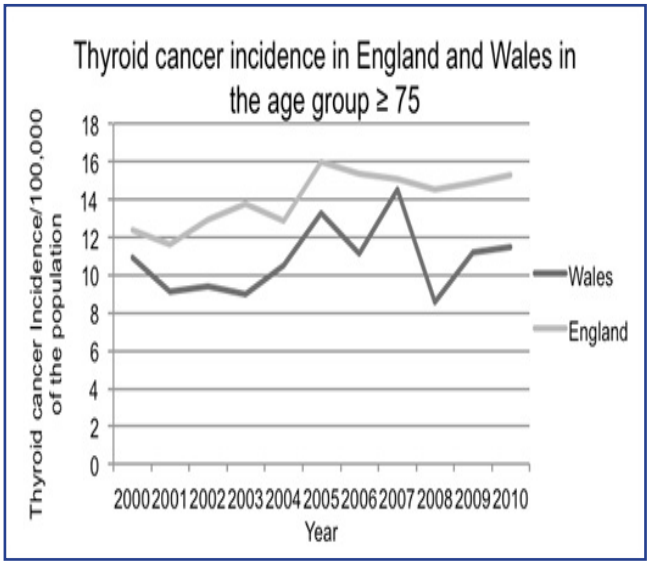

Fig.4. Incidence of Thyroid Cancer in > 75 years age group

Discussion

These data demonstrate that there has been a significant and progressive increase in the incidence of thyroid cancer in adult patients from 2000-2010. The greatest increase was observed in those aged ≥60. However the mortality rate in England has remained relatively static.[7]

There have been previous comments on the validity of HES and PEDW data, which is frequently entered by non-medically trained personnel. However it has been demonstrated in systematic reviews that there is a good correlation between reported and actual validated data, with an estimated coding accuracy of 88 to 92%.[8,9]

Although this study does not directly address the underlying reasons for this increase in thyroid cancer incidence it is important to consider all factors. Radiation is an established risk factor; nuclear weapons testing in the 50's and 60's and the Chernobyl disaster in the 1980's make a good argument for the possibility that radiation is to account. However some who have considered the geographical distribution of thyroid cancers have felt that the areas with a high incidence of disease is inconsistent with exposure to radioactive fallout and that this makes radiation an unlikely major causative factor.[6,10]

The influence of female hormones and reproductive factors on the thyroid has also been debated due to the high proportion of young females that develop thyroid disease. One report suggests that women who had irregular menstruation and women who have undergone a bilateral oophorectomy were at greater disease risk.[11] However many reports are inconclusive or show no link between the two, with calls for further research to be completed on the subject.[4,5]

Another possible explanation is that the widespread accessibility and use of imaging has lead to an apparent increase in thyroid cancer numbers. Of the cancers newly diagnosed it is noted that there has been an increase in the number of small papillary thyroid cancers.[1,2,3] This coinciding increase[2,7] may lead us to suggest that we are detecting a greater number of patients who may have subclinical disease. Higher incidences of thyroid disease has also been seen in patients of a higher socioeconomic status and in patients with health insurance cover.[12,13] As a result these patients will have increased access to imaging.[12]

The management of small thyroid tumors poses a number of difficulties with regards to diagnosis and management of the patient.[14] Some small tumors that are asymptomatic remain dormant in the general population and do not manifest. Ultrasound fine needle aspiration biopsy permits the identification of cancers smaller than 1 cm.[14] Although it is beneficial to catch disease at an early stage the implications of how we discuss the risks and benefits of surgery and anesthesia in the context of the natural progression of the disease should be considered. The cost implication and the capacity for long term follow up also need to be addressed. This is especially important in the context of an aging population often with a range of other comorbidities.[15] The incidence of thyroid cancer increases with age.[15] Our data has shown the increase in incidence in the over 65 age groups to be the greatest, despite the fact that papillary cancers present more commonly in the 30-50 age group.[15] With a population that has aged significantly during the last two decades and that is predicted to increase further during the next two decades,[16] this may present further challenges in managing these patients.

Conclusion

These data confirm that there has been a significant increase in thyroid cancers in adult patients over the last decade (2000-2010). The reasons for this are likely to be a result of a greater diagnostic scrutiny but may also be multi-factorial. The long-term trend and effects of this increasing intervention remains to be seen. An increase in surgical demand and the coinciding ageing population highlights the importance of further investigation into the etiology, use of imaging, patient demographics, histology and overall mortality of this patient group.

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Use of Nasal Obstruction Symptom Evaluation Scale in Objective Evaluation of Symptomological Improvement in Post Septoplasty Patients

Mukulika Saha,[1] Shoham Banerjee,[1] Rabi Hembrom,[1] Indranil Sen[1]

ABSTRACT

Introduction

The complaint of nasal obstruction or difficulty in nasal breathing is highly subjective.

Benefits of Septoplasty, as perceived by the patient, also varies widely with subjective satisfaction ranging from complete alleviation of symptoms to a total failure.

Materials and Methods

Fifty three patients above 18 years of age, with anatomical deviation of the nasal septum as the sole cause of obstruction and symptoms persisting for more than 3 months, underwent septoplasty. Nasal endoscopy was done for Mladina typing of the nasal septal deviation. Pre and post operative NOSE (Nasal Obstruction & Symptom Evaluation) score were analysed.

Results

Mean preoperative NOSE score was 11.98 ±1.23. On the 6th and 12th postoperative week follow up NOSE score was 3.13±1.30 & 1.05±0.87 respectively with p value <0.05.

Conclusion

Mladina typing along with NOSE score will help in letting the patient know about his or her expected outcome following septoplasty.

Keywords

Nasal Obstruction; Nasal Septum; Quality of Life; Patient Satisfaction

Nasal obstruction or difficulty in nasal breathing is a highly subjective sensation and it is a common complaint in rhinological practice. Although there are several aetiologies, like mucosal congestion, nasal mass, turbinate hypertrophy etc, deviated nasal septum (DNS) itself, forms one of the common causes of nasal obstruction. Mladina classifies septal deformity in to 7 types on the basis of their orientation in vertical and horizontal axes (Fig. 1).[1]

As per a recent international study, almost 90% of the subjects showed one of the 7 types of septal deformity.[2] Most of the subjects with DNS are asymptomatic but when they are symptomatic, the definitive treatment is universally accepted as surgical correction or 'septoplasty'. However, the benefits of septoplasty, as perceived by the patient, widely vary over different grades of satisfaction, ranging from complete alleviation of symptoms to a total failure. Pre and post operative assessment of symptoms are necessary for outcome analysis. It is possible to assess nasal obstruction objectively by Rhinomanometry and Acoustic Rhinometry.[3,4] However, most of the time it is found that pre and post operative symptoms of patients do not correlate with the physical finding and objective measurements.[5] As patient's perception of nasal airflow is of primary concern, the improvement in subjective score of patient's symptoms is definitely an important outcome parameter of management plan in order to

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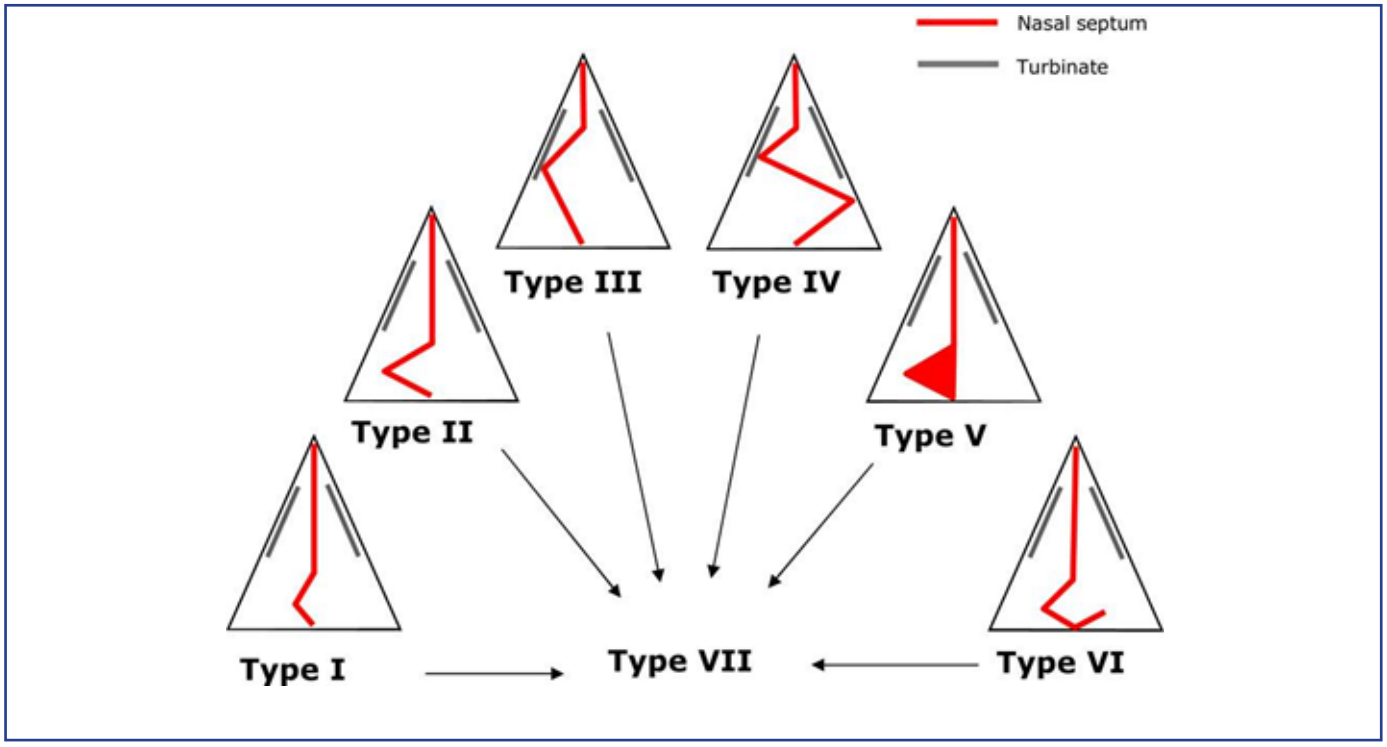

Fig.1. Schematic diagram of Mladina classification of deviated nasal septum

address the complex problem.

NOSE (Nasal Obstruction & Symptom Evaluation) scale was introduced by Stewart et.al in 2004 (Table I).[6] This is a disease specific quality of life instrument for subjective assessment of nasal obstruction. It is in a form of a questionnaire containing five symptoms in increasing severity.

Table I : NOSE (Nasal Obstruction & Symptom Evaluation) scale[6]

	NOT A PROBLEM	VERY MILD PROBLEM	MODERATE PROBLEM	FAIRLY BAD PROBLEM	SEVERE PROBLEM
Nasal congestion/ stuffiness	0	1	2	3	4
Nasal blockage/ obstruction	0	1	2	3	4
Trouble breathing through nose	0	1	2	3	4
Trouble sleeping	0	1	2	3	4
Unable to get enough air through during exertion	0	1	2	3	4

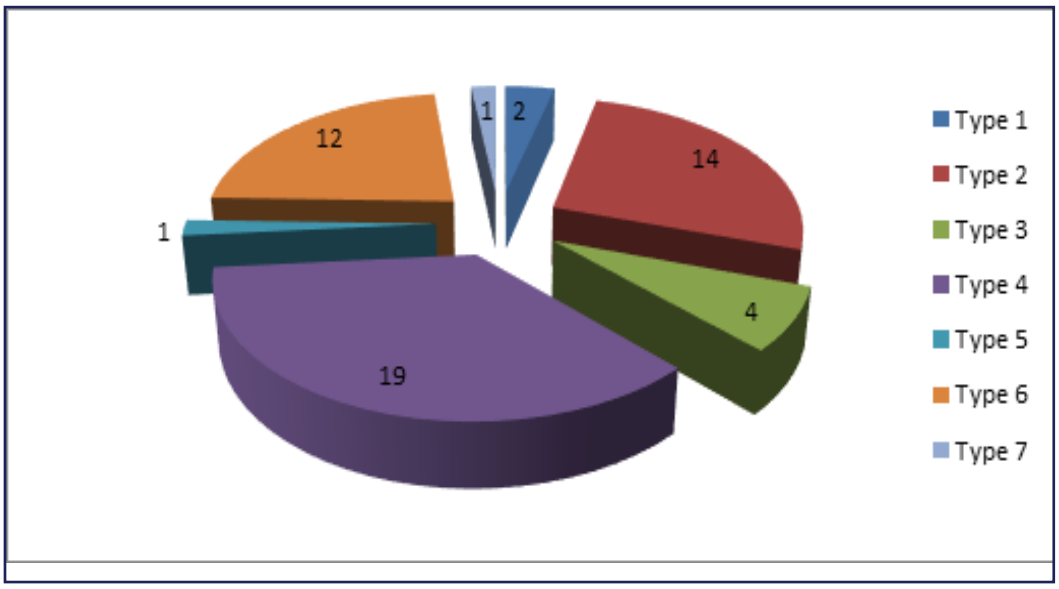

Fig.2. Distribution of types of nasal septum deviation according to Mladina classification

Materials and Methods

This prospective observational study was conducted between September 2014 and September 2015 in a tertiary care hospital to assess the benefits of septoplasty in terms of patient satisfaction in different types of DNS, documented with the help of the NOSE Scale Score. Ethical clearance for the study was taken from Institutional Ethics Committee. Inclusion criteria were age more than 18 years, identifiable anatomical deviation as the sole cause of obstruction, symptoms persisting for more than 3 months, failure of medical management (topical nasal decongestants and steroids, oral antihistaminics and decongestants). Exclusion criteria were sinonasal malignancy, h/o radiation to head neck region, septal perforation, h/o nasal trauma in the last year, adenoid hypertrophy, uncontrolled asthma, septoplasty performed with concurrent sinus surgery.

A detailed and comprehensive evaluation of each patient was made, nasal endoscopy was done for Mladina typing and preoperative NOSE score was noted in patient's own language. All patients underwent septoplasty. Nasal polyvinyl alcohol sponge packs were placed for 48 hours and all patients received parenteral antibiotic. All patients received standard postoperative care. NOSE score taken at 6th and 12th post operative days. The results of our study were analysed on SPSS statistical software package version 20 by using paired't' test.

Results

In our study of 53 patients aged between 18-52 years, 38 patients were male and 15 were female. The majority (19 patients) were of type 4 and least were of type 5 or 7 (1 patient in each type)

Preoperatively, the NOSE score was ranging from 2-11 in 20 (37.73%) cases, 12-13 in 27 (50.94%) cases and 14-20 in 6 cases. In 6th post operative week NOSE score of 14(26.41%) patients was 3 and 12 patients in each group was 2 and 4. Only one patient had NOSE score of 6. At 12th post operative week nearly equal percentage (32-33%) of patients had NOSE score of 0, 1, 2. Only two patients had NOSE score of 3. (Fig. 3) Majority of patients (type 4) showed 89.5% improvement in NOSE score (from 12 to 1.25). Type 1 and type 2 showed almost 95% improvement. Type 5 showed 100% improvement. In majority of the patients (50.94%) preoperative NOSE score ranged from 12-13. (Fig. 4) Mean preoperative NOSE score was 11.98 ±1.23. 6th and 12th postoperative week follow up NOSE

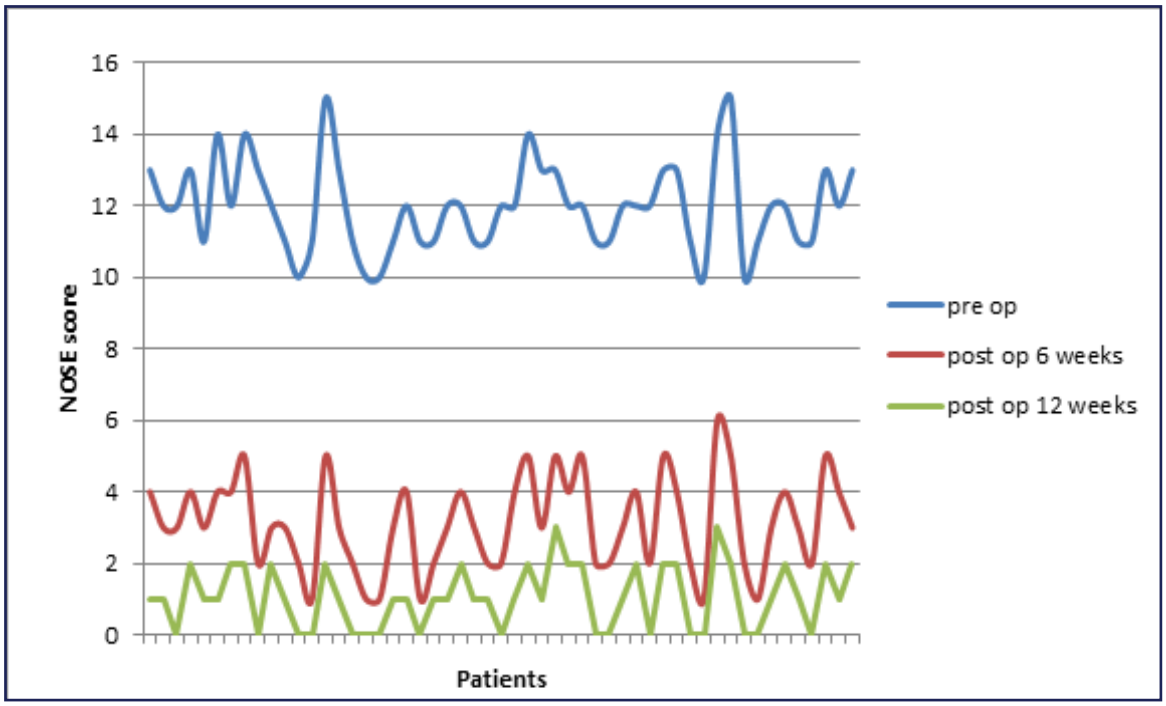

Fig.3. Comparison of NOSE score in the pre-operative period and in the post-operative phase at 6th and 12th week

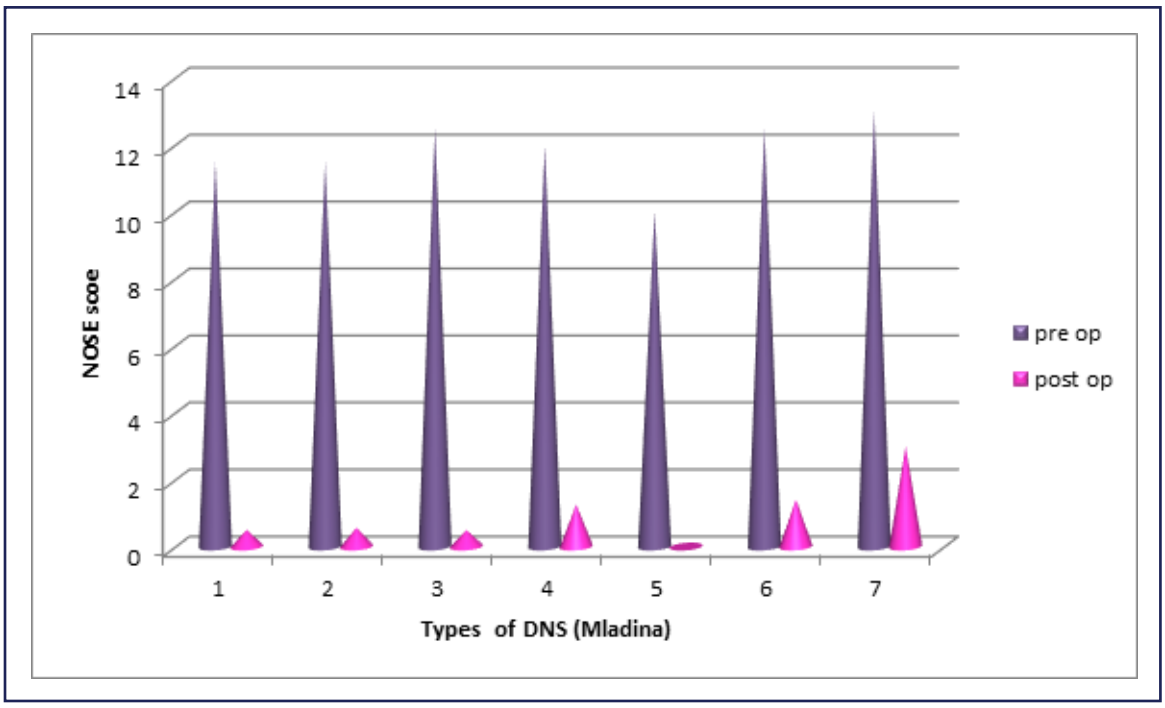

Fig.4. Improvement of NOSE score in different types of DNS (Mladina classification)

score was 3.13±1.30 and 1.05±0.87 with p value <0.05. (Table II)

Discussion

Results of this study almost match with the mean Nose

Table II : improvement of each symptom under NOSE score in different types of DNS (Mladina classification)

SEPTAL DEVIATION MLADINA TYPES		NOSE SCORE (MEAN VALUE)					
		Nasal	Nasal blockage	Trouble breathing through nose	Trouble sleeping	Unable to get enough air through during exertion	Total
1	Pre op.	3.5	3.5	2	1.5	1	11.5
	Post op. 6th wks	1.5	0.5	0.5	0	0	2.5
	Post op. 12th wks	0.5	0	0	0	0	0.5
2	Pre op.	3.42	3.79	2.21	1	1.06	11.48
	Post op. 6th wks	1.07	0.93	0.29	0.14	0	2.43
	Post op. 12th wks	0.35	0.07	0.07	0.07	0	0.56
3	Pre op.	4	4	2	1.5	1	12.5
	Post op. 6th wks	1.25	0.75	0.5	0.25	0.25	3
	Post op. 12th wks	0.25	0	0.5	0	0	0.75
4	Pre op.	3.84	3.95	2.05	1.25	0.89	11.98
	Post op. 6th wks	1.47	1	0.63	0.16	0.16	3.42
	Post op. 12th wks	0.42	0.21	0.47	0.05	0.10	1.25
5	Pre op.	3	3	2	1	1	10
	Post op. 6th wks	0	1	1	0	0	2
	Post op. 12th wks	0	0	0	0	0	0
6	Pre op.	3.92	3.92	2.33	1.17	1.17	12.51
	Post op. 6th wks	1.42	0.83	0.75	0.17	0.33	3.5
	Post op. 12th wks	0.67	0.08	0.42	0.08	0.08	1.33
7	Pre op.	4	4	3	1	1	13
	Post op. 6th wks	1	2	2	0	0	5
	Post op. 12th wks	1	1	1	0	0	3

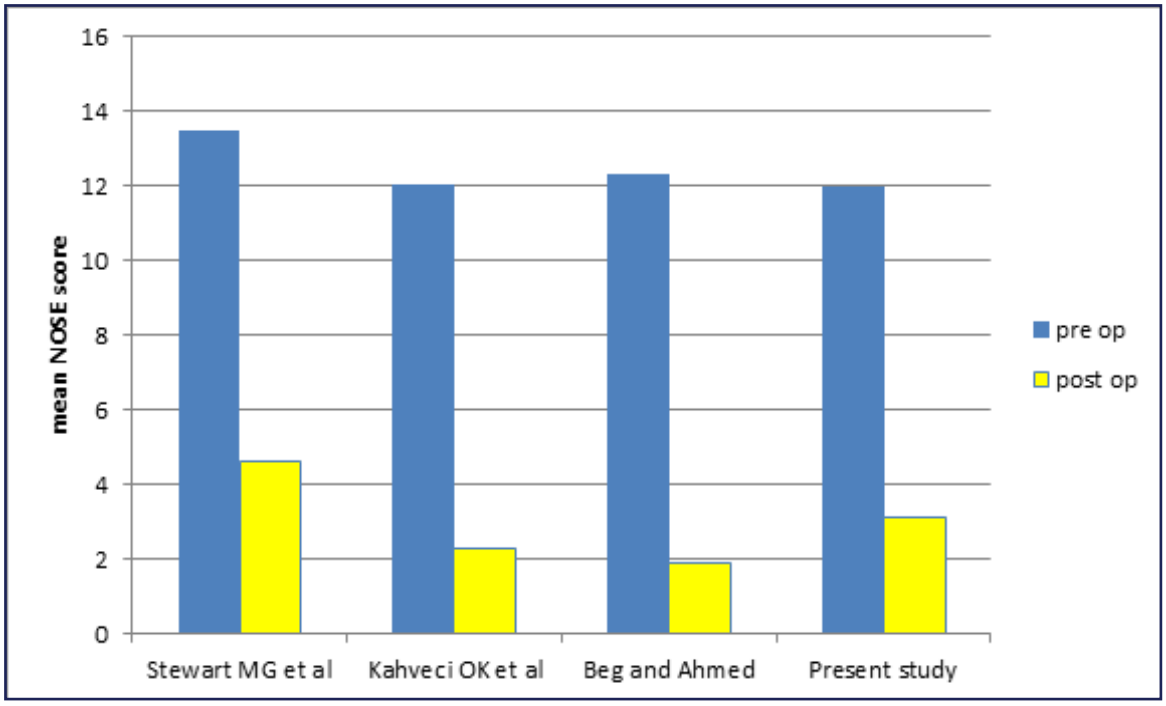

Fig.5. Comparison between mean pre-operative and post-operative NOSE score in different studies

score in the study of Beg and Ahmed,[7] Stewart et al[8] and Kahveci et al.[9] (Fig. 5)

Singla et al[10] in their study uses Mladina system to classify the types of DNS. The most common type was type 5(46%), followed by type 6(16%), type 2(10%), type 4(10%), type 3(8%), type 7(8%), type 1(2%). In present study most common type was type 4(35.84%), followed by type 2(26.41%), type 6(22.64%), type 3(7.54%),type 1(3.77%), type 5 & 7(each 1.88%).

Conclusion

The definitive treatment of deviated nasal septum (DNS) is the universally accepted surgical correction or septoplasty. However the benefits of septoplasty, as perceived by the patient, widely vary over different grades of satisfaction, ranging from complete alleviation of symptoms to a total failure. Mladina typing along with NOSE score will help in letting the patient know about his or her expected outcome following septoplasty. Maximum improvement (100%) was seen in type 5 though there was only one patient in this type and type 7, the complex type of DNS, showed not so satisfactory outcome compared to other types of DNS.

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Hypothyroidism – An Underestimated Complication After Hemithyroidectomy: A Preliminary Study Report

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ABSTRACT

Introduction

Hypothyroidism is a significant but an under-appreciated complication of hemithyroidectomy. The focus of this study was to assess the incidence of hypothyroidism occurring after hemithyroidectomy, identify the risk factors and to suggest a possible follow-up guideline for diagnosis.

Materials and Methods

An institution based preliminary study was conducted in the Department of Otorhinolaryngology, in a tertiary care hospital, from August 2014 to December 2015 on 25 patients. The patients were regularly followed up in 1st month, 3rd month, 6th month, 9th month and 1 year period with the thyroid function test.

Results

Incidence of hypothyroidism occurring after hemithyroidectomy including transient and permanent cases is 32%. Increased age of presentation, longer duration of thyroid swelling, pre-operative serum TSH level >2.5 mIU/ml, lymphocytic infiltration in histopathology and right sided hemithyroidectomy were found to be the possible risk factors.

Conclusion

It is indicated from this preliminary report that there should be a serial thyroid function monitoring in every post-operative hemithyroidectomy patient, and special attention should be given to the risk group

Keywords

Hypothyroidism, Hemithyroidectomy

Hemithyroidectomy refers to removal of one lobe of thyroid along with the isthmus and pyramidal lobe, if present. Although hypothyroidism after hemithyroidectomy is an under-recognized complication, some recent studies showed that it does exist. The incidence of hypothyroidism after hemithyroidectomy as reported in various literature is between 0 to 43 percent.[1] Hypothyroidism can be either subclinical or overt. Normal serum TSH level is 0.43-4.25 mIU/ml.[2] Subclinical hypothyroidism means elevation of TSH beyond the upper limit of the reference range, with normal free T4 level, without any symptom.[3,4] Overt hypothyroidism means elevation of serum TSH level above the reference range and decrease in free T4 level below the reference range along with clinical symptoms.[4,5] So serum TSH is considered to be the most sensitive and earliest detectable parameter to diagnose post-operative hypothyroidism.[2] There are certain other risk factors which can be assessed pre-operatively and indicate the increased chance of post-operative hypothyroidism.[3] Therefore, identification of these risk factors at an early stage can prevent long term complication of hypothyroidism.

But the incidence of post-operative hypothyroidism after hemithyroidectomy remains unpredictable[6] and a long term follow-up is required to analyze these patients. Differences in opinion still persist regarding the causes, risk factors, and management of hypothyroidism following hemithyroidectomy due to dearth of studies. At present, there is no universal protocol to assess thyroid function after hemithyroidectomy.

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So, the purpose of the present study was to assess the incidence, to find out the causes and risk factors and to work-up a possible follow-up protocol for early diagnosis of hypothyroidism after hemithyroidectomy.

Materials and Methods

An institution based preliminary study was conducted in the Department of Otorhinolaryngology, in a tertiary care hospital, from August 2014 to December 2015 on 25 patients. A preliminary report had been prepared from the study up to December 2015. The patients who were operated between August 2014 and December 2014 were followed up for a period of 1 year.

All the patients who underwent hemithyroidectomy for benign pathology irrespective of age, sex, socio-economic and demographic characteristics were included in the study whereas patients with deranged thyroid profile pre-operatively and/or taking medications for that, or any other medication which interferes with thyroid function status and all thyroid malignancies were excluded from the study. After performing hemithyroidectomy, the samples were sent for histopathology and the patients who required completion thyroidectomy after hemithyroidectomy were also excluded from the study. The patients were regularly followed up in 1st month, 3rd month, 6th month, 9th month and 1 year period with the thyroid function tests and status of thyroid function was assessed post-operatively.

Results

The study was conducted on 25 patients who were followed up periodically for one year. The preliminary results shown below are based on this one year follow-up data.

At the end of periodic follow-up after 1 year, we encountered 5 patients who developed permanent hypothyroidism, including overt and sub-clinical cases. The patient showing sub-clinical or overt hypothyroidism in any of the follow-ups and becoming euthyroid later on and maintaining the euthyroid status for next two or more follow-ups without any supplementation therapy were termed as 'transient case' in our study. The patients having either normal thyroid function status or subclinical hypothyroidism were followed up in regular intervals without imposing any supplementation therapy. Levothyroxine supplementation therapy was started in overt cases only, and they were followed up after 3 months. If they attained euthyroid status, levothyroxine supplementation was stopped. The follow-up of each hypothyroid patient has been individualized and their progression of hypothyroidism in the follow-up period is shown in Fig. 1.

At the end of 1 year follow-up, the overall incidence of permanent hypothyroidism (that includes subclinical and overt cases) was 20% (5 out of 25 patients). Amongst the permanent cases, 2 subclinical (40%) and 3 overtly hypothyroid (60%) cases were found. In the study we also found 3 transient cases out of total study population (12%). The total incidence including temporary and permanent hypothyroidism in the present study was 32%.

On distribution of the patients in different age groups (Fig. 2), most cases of post-operative hypothyroidism were observed in the age group of 46-55 years (2 out of 3 cases, 66.7%) and 36-45 years (4 out of 10 cases, 40%). Patients in the age group of 26-35 years (2 out of 9 cases, 18.9%) showed comparatively less incidence of post-operative hypothyroidism, while in the age group of 16-25 years no case of hypothyroidism was reported.

It had also been observed that the patients having pre-operative mean TSH level >2.5 mIU/ml had more incidence of post-operative hypothyroidism (6 out of 13 patients, 46.2%) as compared to patients who had pre-operative mean TSH level <2.5 mIU/ml (2 out of 12 patients, 16.7%), as shown in Fig. 3. The mean TSH level pre-operatively in all the hypothyroid patients (including transient and permanent, total 8) was 2.87mIU/ml and in the euthyroid patients it was 1.65 mIU/ml.

The incidence of hypothyroidism was more in patients who were having thyroid swelling for more than 10 years (7 out of 17 patients, 41.2%). No case of post-operative hypothyroidism was found in patients having thyroid swelling less than 5 years.(Fig. 4) This

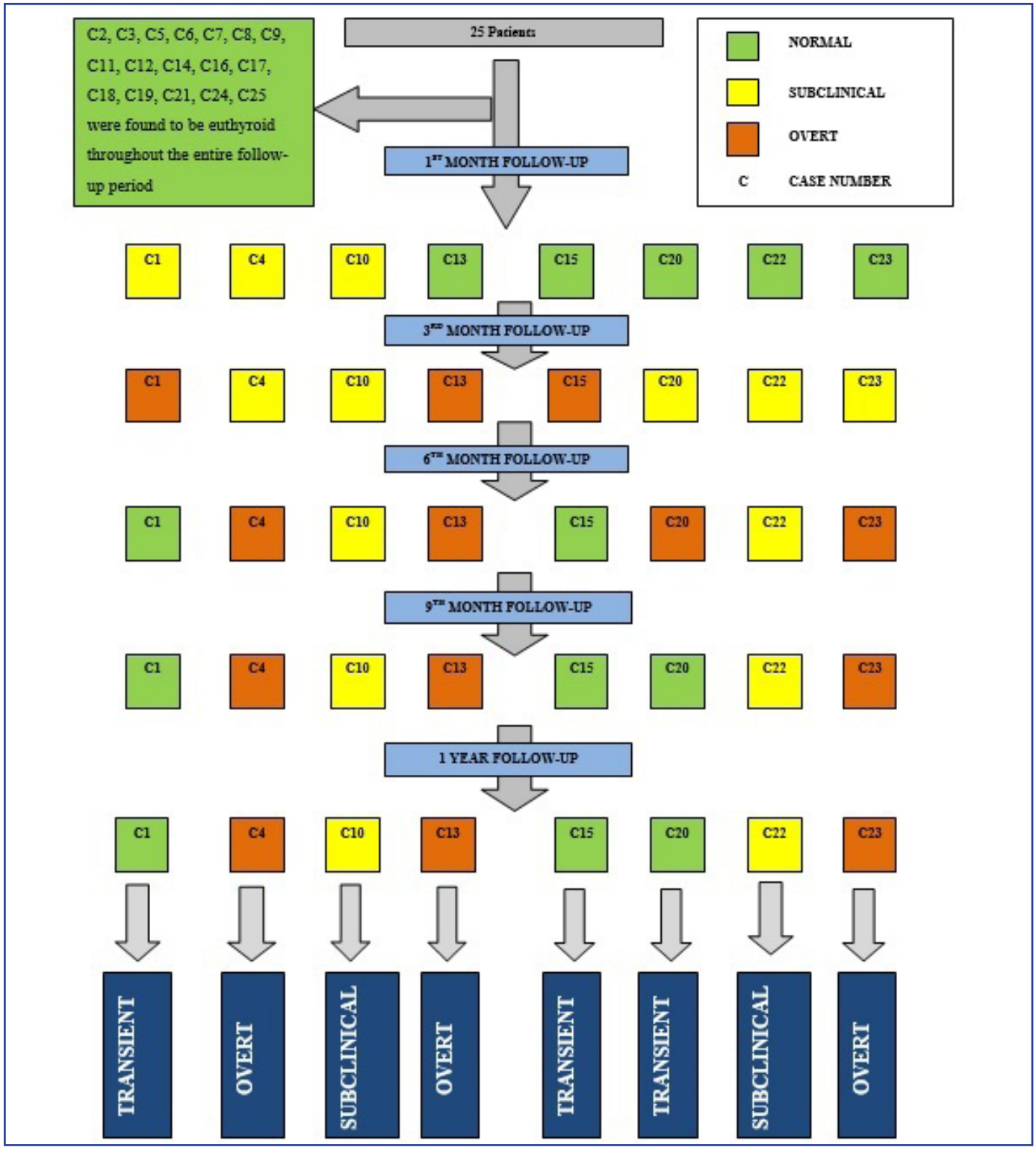

Fig.1. Results of progression of 25 patients in serial follow-up of 1 year

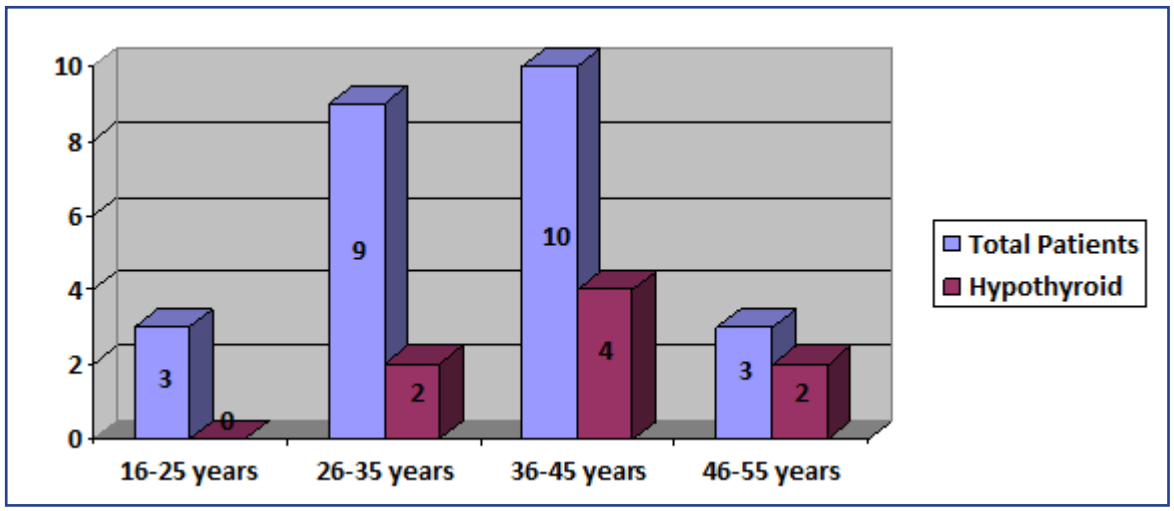

Fig.2. Distribution of patients according to age of presentation

suggests that chance of occurrence of post-operative hypothyroidism is directly proportional to the duration of thyroid swelling.

Histopathological report of each of the 25 patients, when correlated with the incidence of hypothyroidism (Fig. 5), showed that lymphocytic infiltration (4 out of 8 cases, 50%) was most often associated with post-operative hypothyroidism, whereas when histopathology showed colloid goiter, the incidence was less (4 out of 14 cases, 28.6%).

It had also been contemplated that mostly the patients who underwent right-sided hemithyroidectomy were found to develop hypothyroidism (6 cases developed hypothyroidism out of total 13 patients who had underwent right-sided hemithyroidectomy).(Fig. 6)

Thus, from the above analysis, increased age of presentation, higher mean pre-operative serum TSH level, longer duration of thyroid swelling,

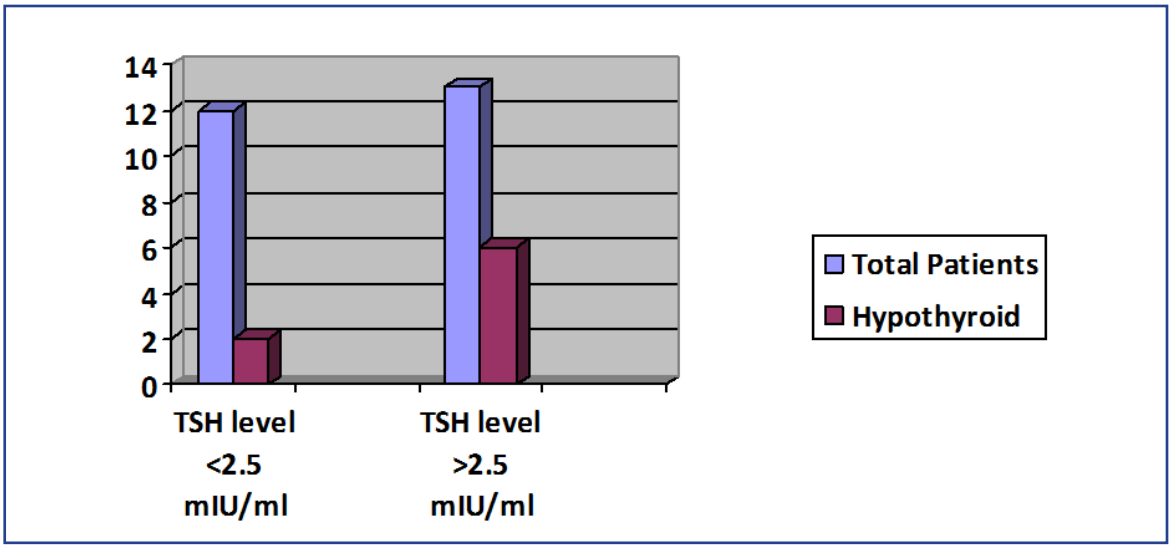

Fig.3. Distribution of patients according to pre-operative TSH level

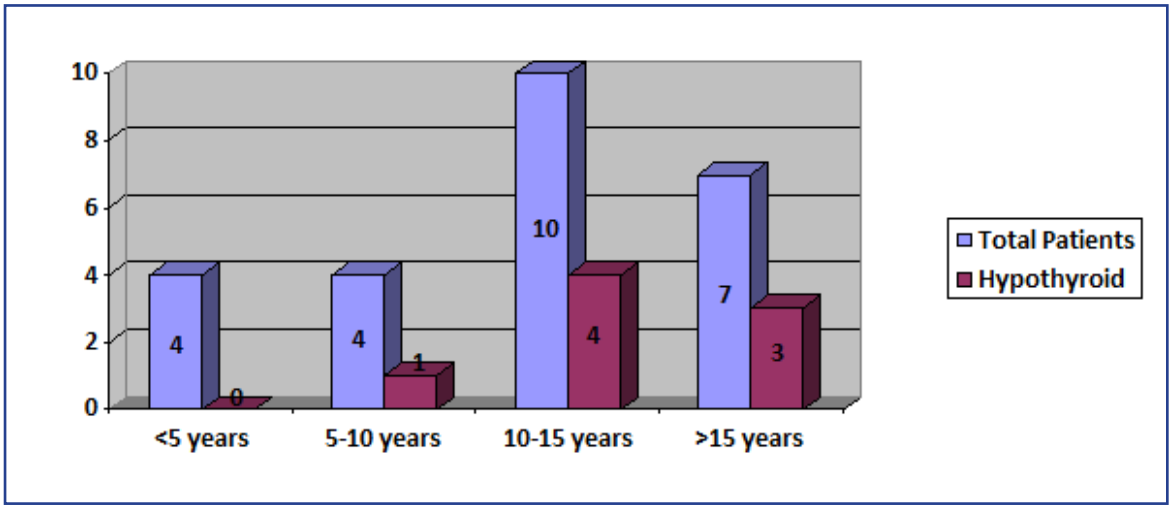

Fig.4. Distribution of patients according to the duration of thyroid swelling

lymphocytic infiltration in histopathology and right-sided hemithyroidectomy can be ascertained as the risk factors for post-operative hypothyroidism after hemithyroidectomy.

Discussion

Hypothyroidism, as a complication to total thyroidectomy, is not uncommon, but hypothyroidism after hemithyroidectomy is a topic of debate not only to otorhinolaryngologists, but also to general physicians and endocrinologists.

Certain literature mentioned that hypothyroidism is unusual after hemithyroidectomy. In reality, transient elevation of serum TSH is possible after hemithyroidectomy due to the remnant thyroid tissue activating the hypothalamo-pituitary-thyroid axis.[7]

Again, another school of thought was to put

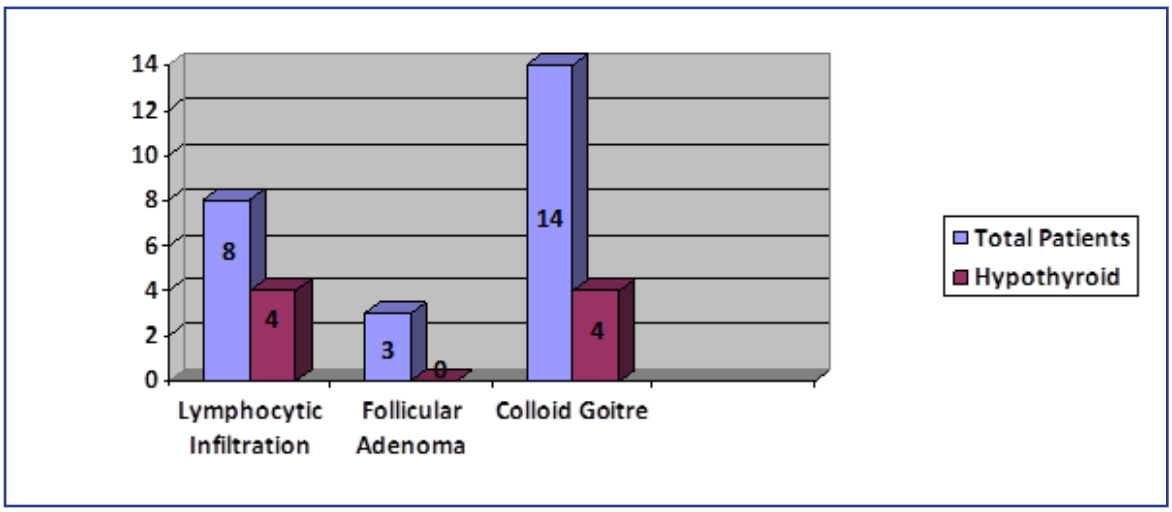

Fig.5. Distribution of patients according to histopathology

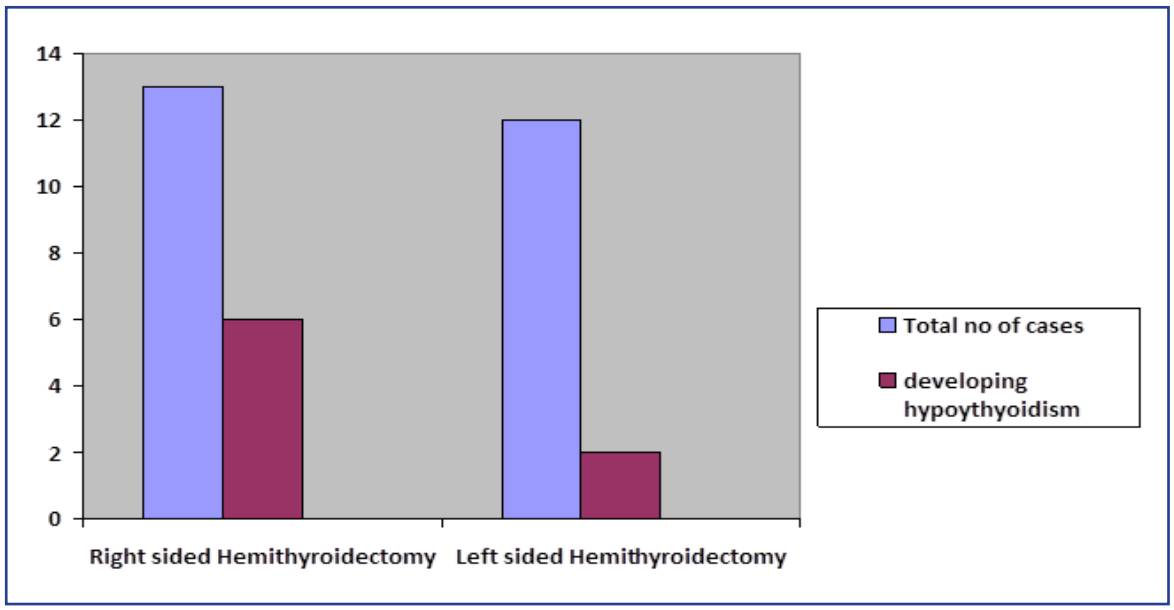

Fig.6. Distribution of patients according to the side of operation

the patients on regular levothyroxine suppression therapy in the immediate post-operative period after hemithyroidectomy,[8] for preventing recurrent thyroid disease. But, it has been seen that levothyroxine therapy will mask the spontaneous recovery of thyroid function in the remaining lobe.[9] Also, due to certain adverse effect of long term thyroid hormone replacement (osteoporosis, atrial fibrillation, etc.)[10] made the practice of regular levothyroxine supplementation obsolete.

Some of the recent researches have documented significant evidence of hypothyroidism after hemithyroidectomy and its association with certain risk factors. Most of the studies show incidence between 15-30%.[1] In the present study, the incidence of post-operative hypothyroidism is 32% (20% permanent, 12% transient). High normal value of pre-operative TSH is a very important predictor of post-operative hypothyroidism.[11] According to Lankarani et al, increased age of presentation, along with prolonged duration of disease are important risk factors as they cause fibrosis of the gland.[12] Side of operation, as per Ying et al and De Carlucci et al, is also a risk factor as because right lobe of thyroid is slightly larger than the left lobe.[13,14] Wormald et al proved in their study that, lymphocytic infiltration in thyroid gland can cause post-operative hypothyroidism.[15] Also there are certain other risk factors as evident in various literatures, like pre-operative detection of thyroid auto-antibodies[16] (anti-TPO and anti-thyroglobulin antibody), body surface adjusted remnant thyroid volume,[17] etc. But in the present study, those factors were not considered as this study is in a preliminary stage and can be considered later on. Early diagnosis is of much benefit by proper identification of the risk factors in the pre-operative period and stratification of the patients accordingly and subsequent meticulous follow-up in the risk group. Long term complications of prolonged hypothyroidism, cardiovascular and neuropsychiatric, such as pericardial effusion, left ventricular hypertrophy, Alzheimer's disease, myxoedema madness[18] can be avoided if the patients are diagnosed in time.

The long term adverse effects are more dangerous in subclinical cases if not followed up properly.[8] And therefore, the patients with subclinical hypothyroidism should be closely monitored for symptoms of hypothyroidism by serial follow up. As per various literature, routine thyroid hormone replacement is not recommended for cases of subclinical hypothyroidism with TSH <10 mIU/L and without signs/symptoms as in long term follow-up most of them returned to euthyroid state.[19,20,21] In the present study also, there were cases of subclinical hypothyroidism who spontaneously

became euthyroid without any particular intervention. We also got two cases of subclinical hypothyroidism, who continued to be subclinical till 1 year follow-up, and they are still under monitoring.

We should wait at least four to five half-lives of serum TSH (t½ of serum TSH = 7 days) before post-operative measurement of thyroid function[22] as the thyroid hormone reserve maintains the euthyroid status. That is why, in the present study, the first measurement of serum TSH has been done at the end of the first month.

In the present study, there are few patients who had been detected to be hypothyroid in the early follow-up and progressively became euthyroid later on. So, the measurement of thyroid function only once at a relatively earlier stage without any further follow-up only diagnoses transient compensatory hypothyroidism and the true incidence remain unclear.[1,8] A serial serum TSH measurement identifies those individuals who continue to remain biochemically hypothyroid and become symptomatic in long term and therefore require treatment with levothyroxine supplementation. The definite follow-up protocol is yet to be established, but the present study has successfully followed a protocol of monitoring the patients at 1st month, 3rd month, 6th month, 9th month and 1year post-operative period.

Although the present study has shown that hypothyroidism is not at all an unusual occurrence after hemithyroidectomy and there are certain risk factors, but as this is a preliminary report of an ongoing study, it will be too early to comment on the statistical significance. Longer duration of follow-up as well as inclusion of more parameters and further analysis will definitely strengthen the association between hypothyroidism and hemithyroidectomy and build a definite follow-up protocol. In the present scenario, awareness is called upon regarding this under-appreciated complication of hemithyroidectomy among all otorhinolaryngologists, general physicians and endocrinologists.

Conclusion

It is indicated from this preliminary report that there is a significant incidence of hypothyroidism occurring after hemithyroidectomy. The chance of developing post-operative hypothyroidism can be predicted from pre-operative assessment of certain risk factors, like, increased age of presentation, higher mean pre-operative serum TSH level, longer duration of thyroid swelling, lymphocytic infiltration in histopathology and right-sided hemithyroidectomy. For diagnosis, there should be a serial thyroid function monitoring in every post-operative hemithyroidectomy patient. At present scenario, awareness is mostly needed regarding this under-appreciated complication of hemithyroidectomy.

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Tinnitus Among Medical Students Using Personal Sound System

Syam Sasidharan,[1] Sheetal Rai,[1] Gangadhara Somayaji[1]

ABSTRACT

Introduction

Statistical data on prevalence of tinnitus in India and on the relationship between exposure to recreational sound/music and the presence of tinnitus are scarce. This study was conducted to assess relationship between tinnitus and the use of personal sound system(PSS) in medical students.

Materials and Methods

A questionnaire based study was conducted on 100 randomly selected medical students to assess their sound habits with the use of PSS. Information on commonly used intensity, frequency, duration of use, type of earphones and severity of tinnitus was sought. Conventional frequency audiometry (0.25-8kHz) was also performed.

Results

The prevalence of tinnitus was found to be 33%, which was on the higher side of the global prevalence data. All the medical students surveyed in this study used personal sound system. Majority of the students (45%) used PSS less than 1 hour daily. More than 60% of the students complaining of tinnitus preferred louder settings in their PSS.

Discussion

The most common personal sound system used was mobile phones. No statistically significant association was seen with relation to the type of personal sound system, the type of ear phone used, average duration of use and hearing loss. Tinnitus was found to have statistically significant association with volume in our study with majority having tinnitus listening to higher levels of sound.

Conclusion

Use of personal sound system is common in medical students. Though duration of use of the personal sound system was not associated with the complaint of tinnitus, exposure to louder sounds had statistically significant association with tinnitus.

Keywords

Tinnitus; Students, Medical; Cell Phones; Leisure Activities; Noise.

Tinnitus is defined as a sound perceived for more than 5 min at a time, in the absence of any external acoustic stimulation of the ear and not occurring immediately after exposure to loud sound.[1] Common causes for it are ear diseases (conductive and sensorineural hearing loss), neurologic disease, bone/joint disorder, endocrine/metabolic diseases, mental disorders, ototoxic drugs, temporomandibular joint disorder or unknown.[1]

Tinnitus is classified into two types, objective and subjective. Objective tinnitus is the sounds or noises that can be heard by others as well as the sufferer with or without the need of a stethoscope or other forms of noise amplifying instrumentation.[2] It can be because of a vascular phenomenon or due to the spasm of the muscle of the middle ear or the palate. In patients with tinnitus it is present in less than 1%. Whereas in subjective tinnitus, the neural signals responsible for tinnitus, may be produced by a lesion in the cortex itself or in the auditory pathway.[2]

Worldwide prevalence statistics indicate that 10% to 33% of the population has tinnitus.[3,4] Although there is positive relationship with age, according to some studies 75% of adolescents had experienced at least a single episode of tinnitus.[5]

The popularization of Personal Sound System (PSS)

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because of its low price, increased storage capacity, easy downloads and reduced size of the devices has increased over time, especially among the younger population. A survey of 18-25 year olds in Nottingham (UK) revealed that, listening to various devices made up 58% of the total average leisure-time activity.[6] Similarly studies have shown that 94.3% of Korean adolescents used personal music players[7] and 66.7% of college students used iPods in USA.[8]

Given that tinnitus can be due to temporary or permanent noise-induced hearing loss, and it can act as a warning sign even before the hearing loss becomes apparent, we sought to study the relationship between exposure to recreational sound and the presence of tinnitus. It will also form a baseline data for further research in understanding tinnitus in the younger people.

Materials and Methods

The study was conducted on medical students of an urban Medical College in Karnataka. Ethical clearance was obtained for this study. A sample size of 100 was selected and subjects were selected by random sampling. Students with pre existing ear disease, previous ear surgery, those with active upper respiratory infections and nasal allergy, pregnant and breast feeding women, those with systemic illness, those with noise trauma and those on medications (antibiotics, diuretics, antimalarials, cytotoxic drugs and analgesics) were excluded.

Students who were selected for the study was asked to fill a questionnaire which included demographic data, containing open and closed questions - addressing their sound habits with the use of PSS, information on commonly used intensity, frequency and duration of use, type of earphones, and symptoms associated with exposure, highlighting the presence of tinnitus. A detailed ENT evaluation was followed by Pure Tone Audiometry conducted in a sound treated room using a calibrated clinical audiometer.

Statistical analysis was done using Chi square test and Pearson correlation.

Results

All the 100 subjects were found to be using personal sound system and prevalence of tinnitus was found to be 33 percent. The most common personal sound system used was mobile phones (45%). (Table I, p value = 0.4) No statistically significant association was found with the type of personal sound system. The most common tool used for hearing was earphones. 38 % used earphones alone, while 24 % used earphones along with speakers and 18% used earphones and headphones. (Table II, p value = 0.455) There was no statistically significant association between tinnitus and tool used for hearing. In earphones, 45% used insertion type of earphones, 40% used both insertion and earmuffs, 13% used ear muffs alone. There was no statistically significant association between tinnitus and the type of ear phone used. (Table III, p value = 0.364) 45% of the students surveyed used PSS for less than 1 hour, 29% used it between one to three hours, 18% between three to five hours & 8% for more than 5 hours. (Table IV, p value = 0.576) There was no association between tinnitus and daily use time. 50 % students surveyed showed the usage of PSS to be more than 5 years. (Table V, p value = 0.414) There was no statistically significant association between tinnitus and total use of PSS in years.

The daily use time was one to three hours in majority (35%) of subjects using personal sound system for more than 5 years. (Fig. 1) There is statistical association between tinnitus and volume of usage. Though majority was using low volume of one to three (77 %), the majority of tinnitus positive patients (61%) were using a high volume in their PSS. (Table VI, p value = 0.00) and Fig.2) There was no statistically significant association between the use of PSS and hearing loss. (Table VII, p value = 0.240) It was found that 11 % had bilateral conductive hearing loss, 2 % unilateral conductive hearing loss and 2% had unilateral sensorineural hearing loss.

Discussion

The prevalence of subjective tinnitus in our study was found to be 33%. In a similar study done on students of

Table I : Tinnitus and type of personal sound system

			TYPE OF PERSONAL SOUND SYSTEM									TOTAL
			ALL	IPOD	MOBILE	MOBILE/ CD PLAYER	MOBILE/ IPOD	MOBILE/ MP3 PLAYER	MOBILE/ MP3 PLAYER/ IPOD	MOBILE/ MP3/ IPOD	MOBILE/MP3/ IPOD/ CD PLAYER	MOBILE/ MP3 PLAYER/ POD	
TINNITUS	ABSENT	Count	4	0	41	1	8	9	2	0	0	2	67
		%	6.0%	0.0%	61.2%	1.5%	11.9%	13.4%	3.0%	0.0%	0.0%	3.0%	100.0%
	PRESENT	Count	4	1	16	1	4	3	1	1	1	1	33
		%	12.1%	3.0%	48.5%	3.0%	12.1%	9.1%	3.0%	3.0%	3.0%	3.0%	100.0%
TOTAL		Count	8	1	57	2	12	12	3	1	1	3	100
		%	8.0%	1.0%	57.0%	2.0%	12.0%	12.0%	3.0%	1.0%	1.0%	3.0%	100.0%

Medicine, University of Lagos, Nigeria, the prevalence was found to be 22 %.[9] This finding lies within the limits of global prevalence of tinnitus among adults which is between 10 & 33 %.[3,4] However no such statistical data is available for Indian population.

The prevalence of use of PSS was found to be 100 percent in our study. A study conducted in Korea, found that 94.3% of adolescents were using personal music player.7 In USA, 66.7% of college students used iPods.[8]

Our study showed that the most common type of earphone used was insert type (Table III); as also found in UK[6] and Korea;[7] it could be because of their better appearance and lesser price. Researchers have found the insert type of earphones are more hazardous compared to headset type.[10,11] This is attributed to the greater coupling of sound directly to ear in this type of earphone.

There was no statistically significant association between tinnitus and duration of exposure. Majority used PSS less than 1 hour daily (45%), though 50% have been using it for more than 5 years. The reduced

Table II : Tinnitus and Tool used for hearing

			TOOL USED FOR HEARING						TOTAL
			ALL	EARPHONES	EARPHONES & HEADPHONES	EARPHONES & SPEAKER	NOT USING ANY	SPEAKER	
TINNITUS	ABSENT	Count	10	25	10	19	2	1	67
		%	14.9%	37.3%	14.9%	28.4%	3.0%	1.5%	100.0%
	PRESENT	Count	7	13	8	5	0	0	33
		%	21.2%	39.4%	24.2%	15.2%	0.0%	0.0%	100.0%
TOTAL		Count	17	38	18	24	2	1	100
		%	17.0%	38.0%	18.0%	24.0%	2.0%	1.0%	100.0%

daily usage of PSS could be the reason for the lack of significant association. Researchers in Australia also found no significant association between years of use or exposure and tinnitus.[12]

Table III : Tinnitus and type of earphone used

			TYPE OF EARPHONE USED				TOTAL
			BOTH	EAR MUFFS	INSERTION	NIL	
TINNITUS	ABSENT	Count	25	7	33	2	67
		%	37.3%	10.4%	49.3%	3.0%	100.0%
	PRESENT	Count	15	6	12	0	33
		%	45.5%	18.2%	36.4%	0.0%	100.0%
TOTAL		Count	40	13	45	2	100
		%	40.0%	13.0%	45.0%	2.0%	100.0%

Table IV : Daily use time of PSS (in hours)

			DAILY USE TIME (IN HOURS)				TOTAL
			MORE THAN 5	ONE TO THREE	THREE TO FIVE	ZERO TO ONE	
	ABSENT	Count (%)	5 (7.5%)	19 (28.4%)	10 (14.9%)	33 (49.3%)	67
	PRESENT	Count (%)	3 (9.1%)	10 (30.3%)	8 (24.2%)	12 (36.4%)	33
TOTAL		Count (%)	8(8%)	29 (29%)	18 (18%)	45 (45%)	100

Table V : Tinnitus and duration of use of PSS (in years)

			TOTAL USE TIME (YEARS)				TOTAL
			MORE THAN 5	ONE TO THREE	THREE TO FIVE	ZERO TO ONE	
TINNITUS	ABSENT	Count	30	13	16	8	67
		%	44.8%	19.4%	23.9%	11.9%	100.0%
	PRESENT	Count	20	5	4	4	33
		%	60.6%	15.2%	12.1%	12.1%	100.0%
TOTAL		Count	50	18	20	12	100
		%	50.0%	18.0%	20.0%	12.0%	100.0%

Table VI : Tinnitus and preferred loudness of the sound system

			LOUDNESS			
			EIGHT TO TEN (80% to maximum volume)	FOUR TO SEVEN (upto 70 % of maximum volume)	ONE TO THREE (upto 30% of max)	TOTAL
TINNITUS	ABSENT	Count (%)	1 (1.5%)	0 (0%)	66 (98.5%)	67
	PRESENT	Count (%)	20 (60.6%)	2 (6.1%)	11 (33%)	33
TOTAL		Count (%)	21 (21%)	2 (2%)	77 (77%)	100

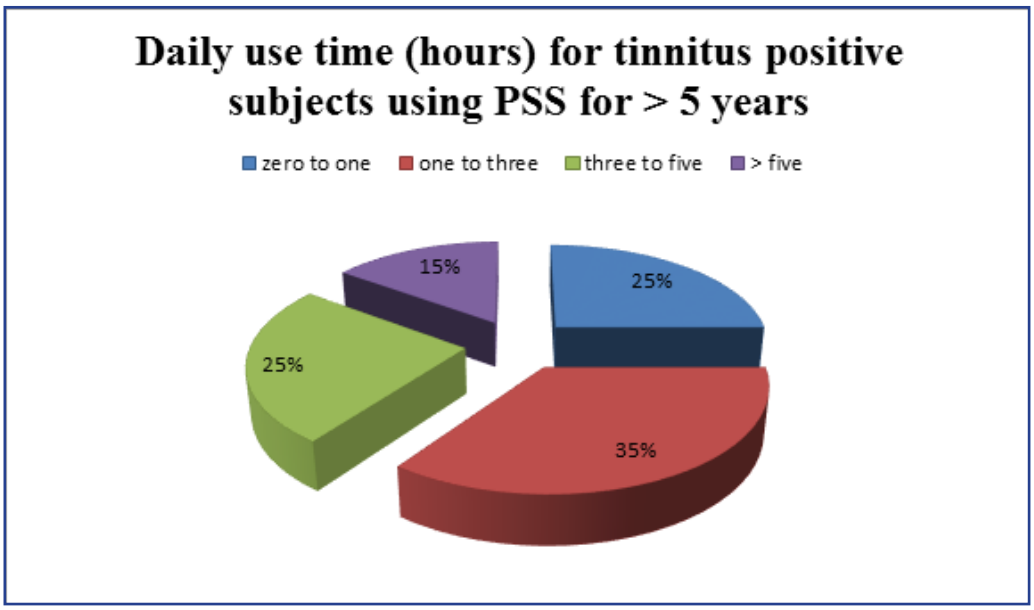

Fig.1. Daily use time (hours) in tinnitus positive patients using PSS > 5 years

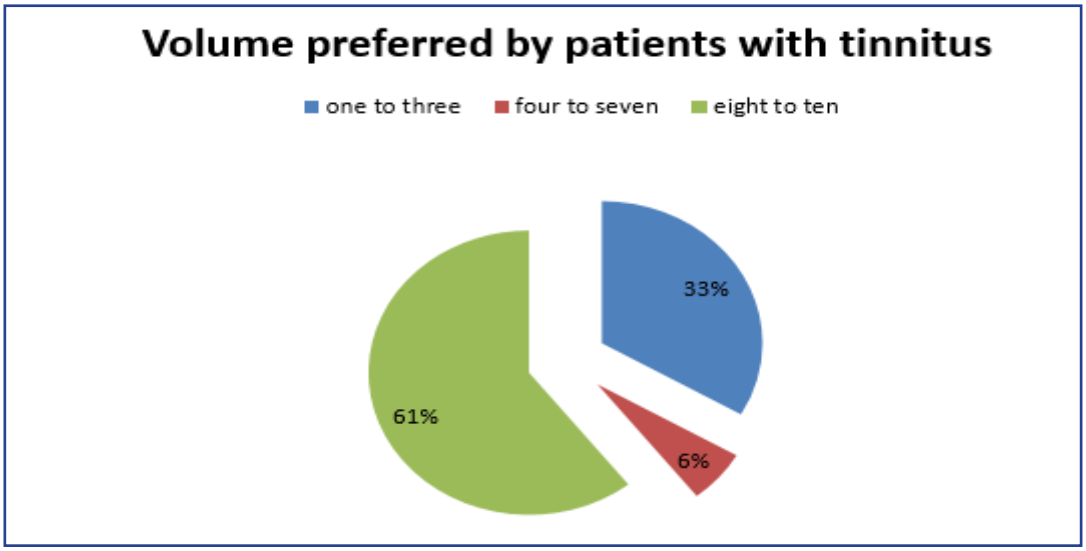

Fig.2. Preferred volume of the sound system in tinnitus positive patients

Tinnitus was found to have statistically significant association with volume in our study with majority having tinnitus listening to higher levels of sound. This association was not established in other similar studies as in the study done on students of Medicine, University of Lagos, Nigeria.[9]

When the severity of tinnitus was asked to be classified as appreciable only in silent environment, continuously present but not affecting the day to day activities or continuously present affecting the day to day activities, all of them felt it as appreciable only in silent environment.

Additionally it was also found that 2% had sensorineural hearing loss, 2% unilateral moderate conductive hearing loss and 11% had bilateral moderate conductive hearing loss. Though there was no statistically significant association, it is estimated that noise induced hearing loss can occur in about 10-30% of

Table VII : Tinnitus and Hearing

			HEARING				TOTAL
			Normal	Bilateral Moderate Conductive hearing loss	Sensorineural hearing loss	Unilateral moderate conductive hearing loss	
TINNITUS	ABSENT	Count (%)	59 (88.1%)	5 (7.5%)	1 (1.5%)	2 (3.0%)	67
	PRESENT	Count (%)	26 78.8%)	6 (18.2%)	1 (3.0%)	0 (0%)	33
TOTAL		Count (%)	85 (85%)	11 (11%)	2 (2.0%)	2 (2%)	100

PSS users after 5 or more years of use, which is due to exposure to the high-intensity noise over a long period of time.[13]

Conclusion

The prevalence of subjective tinnitus in our study is within the limits of global prevalence of tinnitus. No statistically significant associations were found between the presence of subjective tinnitus with the type of ear phone used or duration of use but statistically significant association was seen with the loudness of sound. Further studies in the younger population are, therefore, recommended to fully assess tinnitus.

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Effect of Different Positions of the Head on Tympanometry Results: An Exploratory Study

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ABSTRACT

Introduction

Tympanometry is an objective measure of middle ear function that has been an integral part of the audiological evaluation test battery, for nearly three decades. The parameters of the tympanogram obtained are influenced with many factors such as introduction of positive or negative air pressure, speed of recording tympanogram, etc. This study was aimed to explore the influence of head positioning on tympanometric findings in normal ears.

Materials and Methods

Thirty ears of fifteen normal hearing subjects (mean age 22.8 years) and five ears of subjects (mean age 23 years) with high negative middle ear pressure were selected for the study. Tympanometry was done in four postures: head erect, head bent forward (chin touching the chest), head in supine and head lateralized towards one side.

Results

Two different results were obtained. It was interesting to note that the results significantly changed when the tympanogram was recorded after ten minutes in different head positions compared to those taken immediately after changing the head position.

Discussion

The possible explanation for the effect of duration in different head positions on tympanogram is discussed.

Conclusion

No significant changes were observed on static compliance, middle ear pressure, ear canal volume and pressure gradient when the tympanogram were recorded immediately bringing head in the particular posture. When head was held in the changed position for ten minutes, significant reduction in the pressure gradient was observed. Further extensive studies may be required to document the relationship between head positioning and tympanometric results.

Keywords:

Acoustic Impedance Tests; Tympanogram; Posture

Tympanometry is defined as the dynamic measure of acoustic immittance in the external ear canal as a function of change in air pressure in the ear canal. The peak compensated static acoustic admittance describes the height of the tympanogram measured at the plane of tympanic membrane. This measure is useful because certain disease process can increase or decrease the normal height of the tympanogram. Tympanogram Peak pressure (TPP) is the pressure at which the peak of the tympanogram occurs and is assured to be the point at which the pressure in the ear canal equals the middle ear pressure.[1]

Tympanometry gradient is an objective measure that described the steepness of the slope of the tympanogram near the peak.[1] Several investigators have noted that fluid in the middle ear reduces the gradient of the tympanogram expressed as a ratio[2] and also described that increasing gradient ratios of 0 to 0.3 had increasing sensitivities of 23 to 93% and decreasing specificities of 98 to 38% in identifying middle ear effusion in children scheduled for Myringotomy.[3] Tympanometric width (TW) is another measure used to quantify tympanogram shape

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in the vicinity of the peak and is sometimes also called the tympanogram gradient. Middle ear effusions can widen the tympanogram without substantially reducing the height.[4] No gender differences have been noted[2,5] although TW does increase with advancing age in the adult population.[5] Theoretically, pathologic conditions can either widen or narrow the TW. Although changes in the surface of the tympanic membrane e.g. atrophic scarring and tympanosclerotic plaques[6] can narrow tympanometric width, the only middle ear disorder that has been noted to narrow the TW in ossicular fixation.[1] Middle ear (ME) is a cavity filled with air spaces. If the cavity shape is altered relatively with tympanic membrane, the air, the mass of the middle ear content is influenced on tympanometric finding.[7] It is also found that maintaining head posture in one position prevents or accelerates blood flow and can lead to sense of fullness (increase in pressure) within the head. In view of this, the present study is aimed to explore the influence of head positioning on tympanometric findings in normal persons and cases with middle ear disorders. It was of interest of the authors to determine, whether there are changes in tympanometric results in head positioning in different postures. In this study four postures were used to study variance in tympanometric results.

Materials and Methods

The study was done in four different postures; head erect, head bent forward, supine, and head lateralized towards one side. To observe the effect of duration on tymapanogram two recordings were obtained. The first recording was done in simultaneous posture shift followed by tympanometry. The second condition was posture shift followed by tympanometry after 10 minutes delay. Thirty ears of fifteen normal hearing subjects (mean age 22.8 years) and five ears of subjects (mean age 23 years) with negative middle ear pressure were selected for the study. All the subjects had no history of asthma, hypertension, diabetes, and normal body mass index. Average neck length of the subjects was 10-12cm.

Tympanometry was done in four postures: head erect, head bent forward, supine, and head lateralized towards one side. (Fig. 1) Same procedure was repeated by holding the subjects head in above-mentioned four postures for ten minutes.

Results

Tympanometric tests were done with head held in four different positions. The results of tympanogram parameter obtained in ears without middle ear pathology; immediately in four different head position are shown in Table I.

The mean static compliance, mean middle ear pressure and mean gradient in the four different head position with head held in that position for 10 minutes is shown in Table II.

Inter-examiner reliability was obtained by applying Kappa correlation (r=0.82) in all measured parameters

Table I : Tympanogram parameter recorded immediately in four different head position for normal ears

TYMPANOGRAM PARAMETERS	HEAD ERECT	HEAD BENT FOR-WARD	HEAD IN SUPINE POSITION	HEAD LATERALIZED TOWARDS ONE SIDE
Mean static compliance (ml)	0.833	0.941	0.858	0.875
Mean middle ear pressure (dapa)	15.583	16.251	16.666	17.083
Mean Gradient	74.583	92.916	73.333	66.666

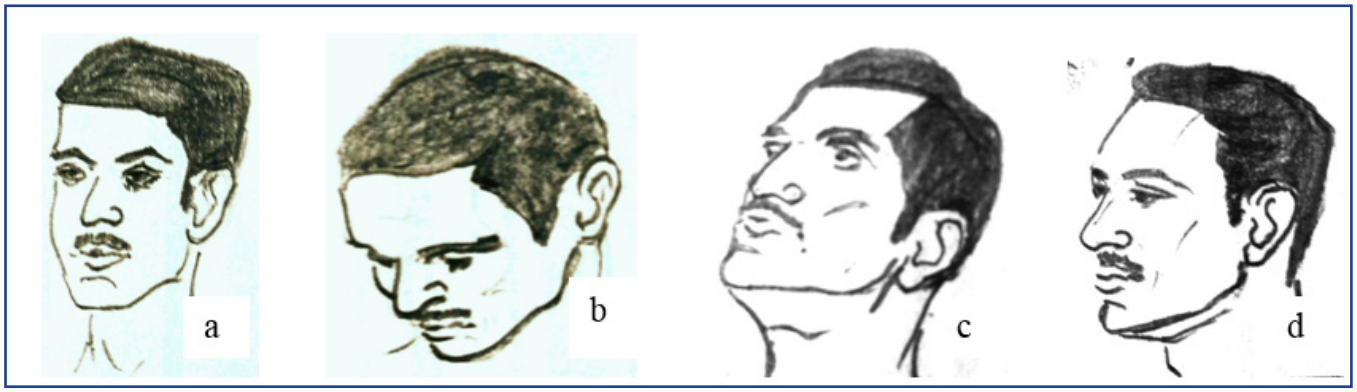

Fig.1. Different postures of the head used in this study

in triplet trials.

Discussion

This study made an attempt to find if the head positioning (head held erect, head bent forward, head in supine position and lateralized towards one side) had any significant changes in normal ears and in cases with middle ear pathology. A similar study on effect of body position in distortion product oto-acoustic emission had reported positive findings.[8] Assuming the volume of a normal ME cleft as 8 mL and following Boyle's law, an ME volume alteration of about 17 mL was required to induce such pressure change.

When the testing was done immediately, there was only change in pressure gradient of tympanogram in various head positions, as seen in Table I. There was a slight increase of pressure gradient (74.583 to 92.916) from head erect to head bent forward position and slight decrease from head erect to head lateralized (74.583 to 66.666). As tympanometric testing takes only few seconds any noticeable change in the physiological or biochemical/gravitational effect may not be observed.

When the head position was held in a particular position and held in that position for 10 minutes the significant changes were observed on at least one parameter of the Tympanogram ($p = 0.05$, t test). From the obtained results it was found that there was a significant change in tympanometric pressure gradient in normal ear as well as in cases with middle ear pathology when compared to head in erect position to head bent forward position. When the head was held in head bent forward position for 10 minutes the pressure gradient reduced by 28.16% (92.916 to 66.75) in normal ears as compared to the pressure gradient in same position

Table II : Tympanogram parameter recorded 10 minutes after head held in four different positions for normal ears

TYMPANOGRAM PARAMETERS	HEAD ERECT	HEAD BENT FOR-WARD	HEAD IN SUPINE POSITION	HEAD LATERALIZED TOWARDS ONE SIDE
Mean static compliance (ml)	0.833	0.850	0.875	0.883
Mean middle ear pressure (dapa)	15.583	15.416	16.250	18.333
Mean Gradient	74.583	66.75	72.083	72.916

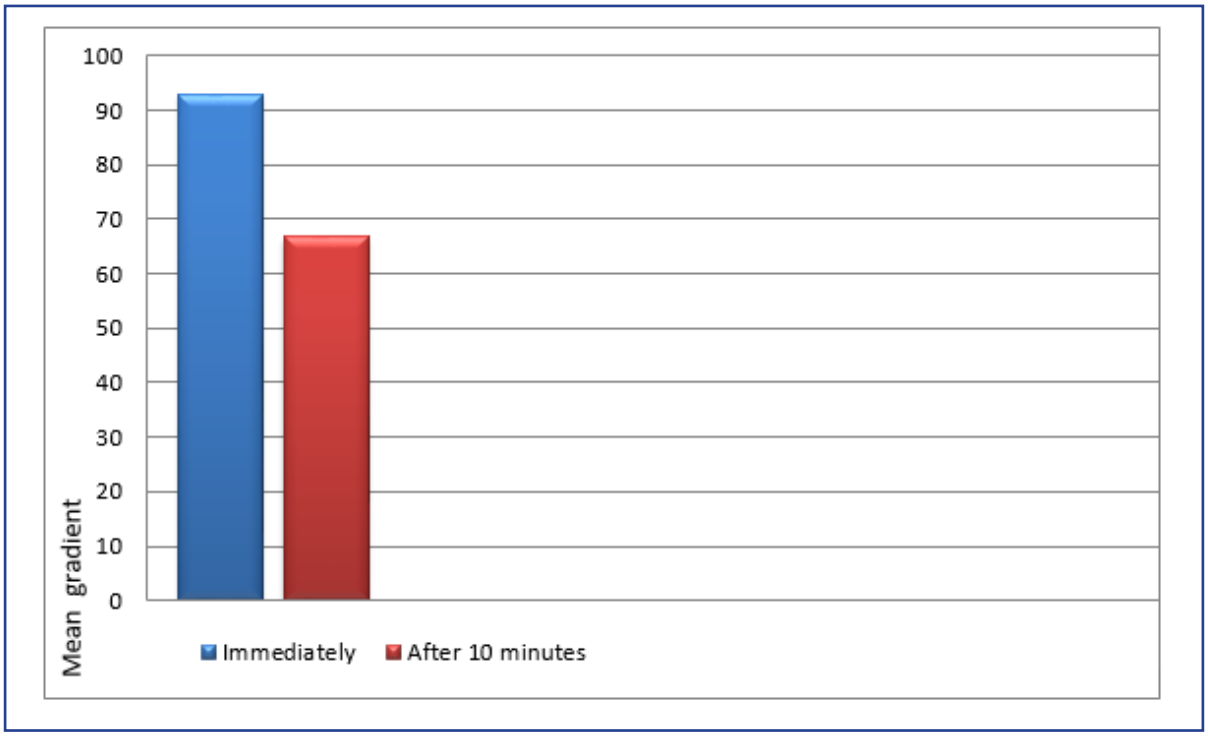

Fig.2. Difference in mean gradient in head bent forward position immediately and after 10 minutes in normal ears

measured immediately. (Fig. 2)

One possible explanation may be that when the head is bent forward and held in that position for 10 minutes the gravitational force may bring on the tympanic membrane extra weight, thus increasing the mass of the middle ear system. It will be interesting to see if any changes in the pressure gradient in cases with fixation of ossicular chain occur.

Other possible explanation is if the blood supply to the ear is reduced, Positional pressure changes were within the range of normal daily ME pressure variations. The instantaneous pressure changes and reversibility may be explained by filling and emptying of blood vessels within the ME cleft, following gravity causing an alteration of the aerated volume. Once a recumbent ear was repositioned upright it demonstrated an immediate pressure drop and regaining the initial ME pressure.[9] Head bent in forward position and held in that position for ten minutes may cause reduction in the blood supply to the middle ear and thus the increase in the mass of the middle ear.[9] However, more evidence has to be gathered before concluding the inferences from this study.

Conclusion

Tympanometric results are known to be influenced by factors like the starting point of the air pressure, recording speed, age and gender.[1,2,7,10] This study was an attempt to observe changes in three parameters of Tympanometric results with different head positions (head erect, head bent forward, head in supine and prone position). No significant changes were observed on static compliance, middle ear pressure, ear canal volume and pressure gradient when the tympanogram were recorded immediately bringing head in the particular posture, however there was significant change in pressure gradient when recorded after 10 minutes. With this exploratory study we hope to generate awareness amongst health care professionals about the variance in tympanogram on differing head positions. This may aid to do further research and help to standardize stringent tympanogram protocol taking head position into account.

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Noise Induced Hearing Loss with Tinnitus: Does TRT Help?

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ABSTRACT

Introduction

To determine if hearing augmentation and tinnitus retraining therapy (TRT) helps in cases of Tinnitus with Noise induced hearing loss (NIHL) and does degree of hearing loss, severity or duration of tinnitus affect recovery

Materials and Methods

A prospective study was done on 100 patients of NIHL with tinnitus from Jan 14-Jul 15. Degree of hearing loss was assessed. Tinnitus severity was scored on Tinnitus handicap inventory (THI) scale as Slight, Mild, Moderate, severe or catastrophic and patients were subjected to TRT. Patients scored after 1 year of TRT. A relation between tinnitus severity, duration and degree of hearing loss on recovery from tinnitus was analysed.

Results

62 of the 100 patients improved following TRT.

Discussion

In 100 patients THI scores improved from a mean of 63.12 (SD-21.12) to 38.16 (SD-18.21). Mean difference between pre and post-intervention THI scores was 24.96 (SD-17.97). Improvement was significant in severe or profound hearing loss (P<.001). Tinnitus severity was slight, mild, moderate, severe or catastrophic on THI. Following TRT, 82.35% with Catastrophic, 70.96% with severe, 52.63% with moderate, 20% with mild tinnitus improved. 1 patient with slight tinnitus did not improve. Based on duration of tinnitus three groups made; 0-6 months, 6-12 months and >12 months. All groups showed improvement. Reduction in Post-TRT THI was significant but did not show any difference among groups.

Conclusion

TRT helps in tinnitus with NIHL particularly if hearing loss is severe. Severe or catastrophic tinnitus patients experience greater improvement. Duration of tinnitus has no impact.

Keywords

Hearing Loss, Noise Induced; Tinnitus

Tinnitus is considered as a phantom sound. It was documented as early as 2-3 millennium BC in dictionary of pharaonic medicine.[1] Many well-known personalities have suffered from distressing symptom including Sappho, Goya, Beethoven and Joseph Toynbee (father of Otology in England). Tinnitus is a type of Dysacusis and could be an objective tinnitus (also called somatosounds- due to an activity outside the auditory system) or subjective tinnitus. The prevalence of tinnitus in general adult population is 10.1 to 14.5%[2] but the number of people suffering due to presence of tinnitus is much less at 7.2%.[3] Various disease processes that may be associated with tinnitus are disorders of ear, neurological, bone and joints, endocrine, mental disorders, cardiovascular diseases and ototoxicity.[4] Of these multiple etiologies the most common pathologies associated with tinnitus are acoustic trauma, Meniere's disease and presbyacusis.[5]

Acoustic trauma leading to Noise induced hearing loss (NIHL) is very common in military service due to frequent exposure to very loud sounds during weapon training/use and tinnitus is a commonly associated symptom. The incidence of tinnitus in acute noise trauma is 100 % and in chronic noise trauma it is 50-90%.[6] NIHL with associated tinnitus or other symptoms like hyperacusis and misophonia (negative emotional response to trigger sounds) can lead to many

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distressing physiological and behavioral symptoms. This results in distressing difficulty in conversation and severely affects the quality of life of these young soldiers.

We carried out a prospective study at a tertiary care military hospital where we studied 100 patients suffering from NIHL associated tinnitus and treated them with hearing augmentation and modified tinnitus retraining therapy (TRT).

Materials and Methods

A prospective study was carried out on patients who presented with NIHL with tinnitus at a tertiary care military hospital from Jan 2014 to July 2015. A total of 100 patients, all males, in the age group 23 to 42 years were enrolled in the study. Individuals who developed NIHL following exposure to loud noise and also had associated unilateral or bilateral tinnitus were included.

Exclusion criteria included patients with middle ear pathology, presbyacusis, history of hypertension and diabetes mellitus, history of exposure to ototoxic drugs and history of head-trauma.

After an informed consent for participation, all patients underwent a thorough ENT examination. Hearing assessment was done using pure tone and impedance audiometry to assess the degree and type of hearing loss. Severity of tinnitus was scored according to the Tinnitus handicap inventory (THI) scale. THI is a 25 item self-report questionnaire introduced by Newman et al (1996) that has functional, emotional and catastrophic subscales.[7] It has specific questions to assess the difficulties faced by the patient due to tinnitus. A typical patient takes approximately 10 minutes to complete the THI and it is completed in presence of an expert who provides an explanation, if required. Scoring THI in a patient takes 5-10 min with a score of 4 given for a 'yes', 2 for 'sometimes' and 0 for 'no'. The THI score ranges from 0 to 100 where a higher score indicates more distress. Though the test was developed in USA but can be used in an Indian setting without any modification.

The THI scores are graded as follows:

- Slight 0-16
- Mild 18-36
- Moderate 38-56
- Severe 58-76
- Catastrophic 78-100

After establishing the grade of tinnitus on THI score, patients were subjected to TRT. Since all our patients belonged to Jastreboff category 2,[8] they were all provided with bilateral digital hearing aids. An ENT surgeon and the speech therapist counselled them every week about the pathophysiology of tinnitus development following noise trauma and its consequences. The patients were then scored on THI after 1 year of TRT.

An analysis was done to study a relation between tinnitus severity and the degree of hearing loss. The effect of TRT on the tinnitus profile of the patient was also analysed. The results were statistically tested using statistical package for the social science system version SPSS 17.0. Continuous variables were presented as mean ± SD, and categorical variables are presented as absolute numbers and percentage. The comparison of normally distributed continuous variables from pre-post TRT was performed using Paired t test. $P< 0.05$ was considered statistically significant.

Results

Total no. of patients enrolled in the study were 100 and were aged between 23 to 42 years (mean=31.01, SD= 4.24). They all underwent a standard audiological assessment and were subjected to TRT.

On basis of degree of hearing loss, they were categorized into 4 categories. 10 (10%) individuals had slight hearing loss and 16, 45, 29 patients had moderate, severe or profound hearing loss respectively (Table I). 62 of the 100 patients showed improvement in their subjective symptoms (62%) (Table II) and THI scores improved from a mean score of 63.12 (SD-21.12) to 38.16 (SD-18.21). The mean difference between pre-intervention and post-intervention THI scores was 24.96 (SD-17.97) and was statistically significant ($p<0.001$) (Table III). However, the improvement was significant

Table I : Frequency distribution based on degree of hearing loss

DEGREE OF HEARING LOSS	FREQUENCY	PERCENTAGE
Slight	10	10.0%
Moderate	16	16.0%
Severe	45	45.0%
Profound	29	29.0%
Total	100	100%

only in those who suffered severe or profound hearing loss and was not significant in those who had only a slight or moderate pre-intervention hearing loss (Table IV).

Patients were categorized as suffering from slight, mild, moderate, severe or catastrophic degree of tinnitus based on THI and there were 1, 15, 19, 31, 34 patients in each category respectively (Table V). Following intervention, 28 of the 34 patients with Catastrophic tinnitus improved (82.35%), 22 of the 31 patients suffering from severe tinnitus improved (70.96%), 10 of the 19 with moderate tinnitus improved (52.63%) while only 3 of the 15 patients with mild tinnitus (20%) improved and the only patient with slight tinnitus did not report improvement (Table VI).

Finally, patients were arbitrarily classified on basis of duration of tinnitus to explore the possibility of its impact on recovery from tinnitus following TRT. Temporal classification had three groups based on duration of tinnitus 0-6 months, 6-12 months and more than 12 months. 21, 50 and 29 patients were found to be there in each temporal group respectively. In the first group (0-6 months) the mean improvement in terms of THI following TRT was 25.43 (SD-21.69), in the second group (6-12 months) 22.72 (SD-16.36) and in the third group (12-24 months) 28.48 (SD-17.74). All these differences between pre-TRT and post-TRT THI values were statistically significant but did not show any significant difference amongst the group.

Table II : Percentage of patients who improved after TRT

THI CHANGE	FREQUENCY	PERCENTAGE
Change	62	62.0%
No change	38	38.0%
Total	100	100%

Table III : Pre-intervention and post-intervention THI scores

	BEFORE TRT (N=100)	AFTER TRT (N=100)	MEAN DIFFERENCE ± SD	P VALUE
	Mean ± SD	Mean ± SD		
THI score	63.12 ± 21.12	38.16 ± 18.21	24.96 ± 17.97	<0.001

Discussion

Tinnitus is defined as an auditory perception due to aberrant spontaneous activity arising from an altered state of excitation or inhibition within auditory system. The auditory system operates by a complex feedback phenomenon which includes an ascending afferent pathway and a descending efferent pathway. It's also connected with central nervous system through other non-auditory structures like limbic system, reticular activating system serotonergic, somato-sensory and hypothalamic system.[9]

The pathophysiology of tinnitus in NIHL is complex and is thought to result from various pathological processes. Some of them are explained here.

Table IV: Pre-intervention and post-intervention THI scores based on degree of hearing loss

DEGREE OF HEARING LOSS	N	BEFORE TRT	AFTER TRT	MEAN DIFFERENCE ± SD	P VALUE
		Mean ± SD	Mean ± SD		
Slight	10	36.40 ± 10.26	22.20 ± 15.45	14.20 ± 14.89	0.015
Moderate	16	46.75 ± 20.95	33.88 ± 20.93	12.88 ± 13.08	0.001
Severe	45	68.62 ± 16.79	40.44 ± 15.51	28.18 ± 18.46	<0.001
Profound	29	72.83 ± 14.56	42.48 ± 18.82	30.34 ± 16.48	<0.001

Following acoustic trauma, pathological changes in cochlea cause reduced auditory input leading to compensatory disinhibition in proximal auditory pathway. This disinhibition results in tonotopic reorganization that, in turn, leads to tinnitus. Another pathological process implicated in NIHL, is down regulation of Gamma amino butyric acid (GABA) in auditory periphery which leads to reduced inhibitory function of the efferent pathway.[10] An alteration in the spontaneous activity and plastic transformation of the brain results from the reduced afferent input and compensatory disinhibition in proximal auditory pathways[11] leading to tinnitus.

Cochlear lesions lead to reduced spontaneous activity in auditory nerve and ventral cochlear nucleus[12] and an increased activity in dorsal cochlear nucleus, inferior colliculus, medial geniculate body and cortical neurons.[13] This neuronal hyperactivity is thought to be the neurophysiological correlate of clinical tinnitus thus demonstrating that tinnitus occurs due to central processing.[14]

Table V : Frequency distribution of patients based on degree of tinnitus

DEGREE OF TINNITUS	NO. OF PATIENTS	PERCENTAGE
Slight (Sligh)	1	1%
Mild	15	15%
Moderate(Mod)	19	19%
Severe	31	31%
Catastrophic (Cat)	34	34%

Various treatment modalities have been tried to treat tinnitus because a fully satisfactory treatment still remains elusive.[15] These treatment modalities include :

- Pharmacotherapy
- Cognitive behavior therapy
- Tinnitus masking
- TRT
- Trans-cranial electric or magnetic stimulation, etc.

Pharmacotherapy includes many different classes of drugs like antidepressants, GABA analogues, Ca-channel antagonists, anti-epileptics, prostaglandin analogues, lidocaine etc.

Lidocaine is one of the most promising drugs for control of tinnitus and probably acts by sodium channel blockage.[16]. Its use is impractical due to intra-venous mode of delivery. In some studies, it has been used successfully by a Trans-tympanic application. In a study by Sakata H et al a Trans tympanic infusion of 4% lidocaine was given in cases of cochlear tinnitus associated with vestibular symptoms and a success rate of 81% was achieved with this therapy.[17]

Gingko biloba, an extract from the leaves of maidenhair plant has been used commonly for tinnitus but its efficacy has not been proved in randomized controlled trials.[18]

Psychotherapy for tinnitus includes cognitive

Table VI : Category-wise improvement on basis of degree of tinnitus

THI CHANGE	FREQUENCY	PERCENTAGE
Cat-Cat	6	6.0%
Cat-Mild	12	12.0%
Cat-Mod	11	11.0%
Cat-Sev	4	4.0%
Cat-Slight	1	1.0%
Sev- Sev	9	1.0%
Sev-Mild	10	10.0%
Sev-Mod	10	10.0%
Sev-Slight	2	9.0%
Mod-Mild	8	8.0%
Mod-Mod	9	9.0%
Mod-Slight	2	2.0%
Mild-Slight	3	3.0%
Mild-Mild	12	12.0%
Slight-Slight	1	1.0%
Total	100	100%

behavior therapy (CBT) and biofeedback. Hallam et al.[16-19] introduced CBT which is based on the psychological model of tinnitus. In this, the negative emotions generated by tinnitus are separated from its perception. Its efficacy has been proved by eight small randomized control trial[20] and also by a review of literature by Cima et al.[21]

Tinnitus maskers have been used for reduction or abolition of tinnitus by sound presentation devices (pillow speaker, MP 3 players) placed either 'behind' or 'in' the ear. They yield a positive result on the negative effects of tinnitus[22] but accurate data regarding their efficacy is not available though they are claimed to provide immediate relief in contrast to TRT.[23]

Trans cranial magnetic stimulation at different frequencies has been also been tried for tinnitus and an objective evaluation done by using THI or self-rating. It has been concluded that daily repeated sessions may be useful for tinnitus.[24]

TRT is based on neurophysiological model of tinnitus.[25] This model suggests that the auditory system has only a secondary role in the distress associated with tinnitus. The distress caused by tinnitus occurs when the auditory activity spreads to the limbic and autonomic system, especially the sympathetic autonomic system. The aim of TRT is to educate the patient regarding tinnitus, try to achieve habituation and remove the negative emotions associated with tinnitus perception.

Jastreboff has divided tinnitus patients in five categories (0-4) on basis of

a. impact of tinnitus on patient's life

b. associated hearing loss perceived by patients

c. problem in sound tolerance

d. effect of exposure to moderate to loud sounds on symptoms

All our patients belonged to Jastreboff Category 2 (tinnitus associated with hearing loss) and were managed with counselling and digital hearing aids.

Clinically distressing tinnitus appears more frequently when the initiating event is associated with high noise level in a setting of background emotional stress as occurs in professions like military, firefighters and policemen etc. In such populations the tinnitus is associated with NIHL and various studies have shown a success rate of 60-70 % with use of hearing aid and TRT.[26]

In our study the patient profile was young male patients (age ranging from 23-42years) who were exposed to loud sounds of gun and artillery fire (sound ranging 156 -180 dB SPL) They presented to us after varying periods of time after the noise exposure. By use of hearing aids and TRT in form of repeated counselling we achieved a success of 62% in reducing distress associated with tinnitus and also improved hearing

acuity. A study conducted by Bartnik G et al evaluated effect of TRT in patients with tinnitus and subjective hearing loss versus those who had tinnitus only. They evaluated 40 patients and found that 90% of patients with tinnitus and subjective hearing loss had significant improvement at after 1 year of therapy.[27] This study has not categorized the patients on basis of degree of hearing loss whereas in our study we have quantified the degree of hearing loss and have assessed the effect of TRT on various categories independently.

A Cochrane review to determine the efficacy of TRT for management of tinnitus was carried out by John S Philips which concluded that THI improved in the range of 18.2-50.4 points this wide variation being the result of considering patients with varying degree of severity of tinnitus as different categories.[28] We found an average improvement in THI score of 24.96 ± 17.97 (Table III). However, this study also did not take in to account the accompanying hearing loss. Baracca GN in a study of 51 patients found that patients who had suffered from tinnitus for less than one year achieved significantly better results than patients who had suffered for a longer period of time and concluded that TRT is an effective tool in the treatment of tinnitus.[29] In our study, the duration of tinnitus did not influence the extent of improvement in THI scores following TRT probably because the maximum duration of tinnitus in our cohort was only 2 years, also the patients in other studies did not suffer from NIHL which was addressed by amplification in present study.

In another study by Henry et al in 2006 revealed no effect of the duration of tinnitus on the effectiveness of TRT.[30] It also stated that degree of hearing loss too, had no impact on TRT results unlike our results where the effect of TRT in cases of slight and moderate hearing loss was notstatistically significant.at p<.001 (However, it would have been significant if we had taken p<.05 and therefore the results are inherently not very different).

There was no improvement in 38% of our patients and this was probably because THI scores are influenced by underlying emotional stress. Most of our patients being young soldiers and having been evacuated from active military zones had high level of anxiety. This may explain a comparatively modest success rate in our study.

Conclusion

Tinnitus frequently accompanies NIHL and adds to patient morbidity. TRT has been found to be effective in reducing this morbidity. However, its multifactorial causation and varied degree of severity makes it difficult to predict possible improvement as also the influence of various factors on degree of improvement. We conducted a study on 100 patients and noticed improvement in 62 of them on basis of a measurable and objective questionnaire based parameter, the THI score. Improvement was statistically significant in cases of severe or profound hearing loss (P<.001).

Tinnitus was classified on basis of its severity into slight, mild, moderate, severe or catastrophic on THI score. Following TRT, 82.35% patients with Catastrophic, 70.96% with severe, 52.63% with moderate, 20% with mild tinnitus showed significant improvement. 1 patient with slight tinnitus did not improve. More severe tinnitus showed greater amelioration of symptoms after TRT.

Based on the duration of tinnitus three groups made; 0-6 months, 6-12 months and >12 months. All groups showed improvement. However, the reduction in Post-TRT THI scores was significant in all three groups but did not show any difference amongst the 3 groups thus indicating that duration of tinnitus did not affect the prognosis.

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Invited Article

Medical Negligence : An Overview

Bratin Kumar Dey[1]

ABSTRACT

Medical professionals are treated as next to God. They provide humanitarian services and gives solace to individuals suffering from various diseases and disorders. Due to their great service to humanity, the doctors and medical professionals are treated with reverence and since the ancient times the medical profession has been considered as a noble profession. However with the passage of time, there has been a change in the doctor - patient relationship.

During the last few decades, a number of incidents have come to light in which the patients have suffered due to the error and inadvertent conduct of doctors. Due to the increasing conflicts and legal disputes between the doctors and patients, most of the legal systems have developed various rules and principles to deal with such inadvertent behavior of doctors. This has led to the development of a new branch of jurisprudence, i.e. medical negligence. Hence, any negligence on part of the medical professional would be treated as either a tort of negligence or a deficiency in service under Consumer Protection Act, 1986. As the profession involves the idea of an occupation requiring purely intellectual skills or of manual skills controlled by the intellectual skill of the operator, it is distinctively different from an occupation, which is substantially production or sale or arrangement for the production or sale of commodities. Medicine is a highly complex domain.

It is difficult for consumer laws to review medical negligence cases with flawless technical clarity and accuracy. Thus medical negligence is not purely a matter of consideration for judiciary but also the technical inputs of specialized experts in the field have substantial weightage while deciding the case of medical negligence against doctors. The present paper is devoted to introvert inspection of negligence in medical profession in the light of existing laws with more emphasis on the interpretation of consumer protection law by judiciary.

Keywords:

Medical Negligence; Malpractice; Liability, Legal; Malpractice

Medical professionals are treated as next to God. They provide humanitarian services and gives solace to individuals suffering from various diseases and disorders. Due to their great service to humanity, the doctors and medical professionals are treated with reverence and since the ancient times the medical profession has been considered as a noble profession. However with the passage of time, there has been a change in the doctor - patient relationship. During the last few decades a number of incidents have come to light in which the patients have suffered due to the error and inadvertent conduct of doctors. Due to the increasing conflicts and legal disputes between the doctors and patients, most of the legal systems have developed various rules and principles to deal with such inadvertent behavior of doctors. This has led to the development of a new branch of jurisprudence, i.e. medical negligence. Hence, any negligence on part of the medical professional would be treated as either a tort of negligence or a deficiency in service under Consumer Protection Act, 1986. As the profession involves the idea of an occupation requiring purely intellectual skills or of manual skills controlled by the intellectual skill of the operator, it is distinctively different from an occupation, which is substantially production or sale or arrangement for the production or sale of commodities. Medicine is a highly complex domain. It is difficult for consumer laws to review medical negligence cases with flawless technical clarity and accuracy. Thus medical negligence is not purely a matter of consideration for judiciary but also the technical inputs of specialized experts in the field have substantial weightage while deciding the case of medical negligence against doctors. The present paper is devoted to introvert inspection of negligence in medical profession in the light of existing laws with more emphasis on the interpretation of consumer protection law by judiciary.

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In the Sanskrit there is famous thought i.e. 'Aarogyam Dhanasampada', which implies 'Health is Wealth', and we all are very cautious about it to some extent. Happiness and health have very close relation, just like sound mind needs a sound body. We try our level best to be fit and healthy. But, sometimes fortunately or unfortunately we get some problems to our health, wherein we needed to take help from doctors. Doctor is considered as a highly responsible person because he can save a life of human being, when the patient is in a critical condition. He has the highest responsibilities over the life of the patient. Since no man is perfect in this world, it is evident that a person who is skilled and has knowledge over a particular subject can also commit mistakes during his practice. Such mistakes in the medical profession may lead to minor injuries or some serious kinds of injuries and sometimes such mistakes may even cause death. Such situations call for a need for remedies to the injured people so that justice is upheld and this gave rise to the concept of medical negligence.

Negligence, in simple terms, is the failure to take due care and caution. It is a breach of a duty caused by the omission to do something, which a reasonable person guided by those considerations which ordinarily regulate the conduct of human affairs, should have done. It may also be doing something, which a prudent and reasonable person would not have done. The essential components of negligence are: 'duty', 'breach' and 'resulting damage'. These definitions are rather relative and can change with the circumstances. When trying to drag a person away from the clutches of an attacking animal, one cannot ask whether this would cause damage to the person's limbs. Doctors can also be faced with similar contingencies. On finding an accident victim in a dangerous condition, a doctor may have to attempt a crude form of emergency surgery to try and save the person's life. No negligence is involved in such cases.

Initially court could not show much interest in such medical negligence matters. But as the time passed and numbers of such incidence increased drastically, judiciary has paid special attention towards it and it is evident from the number of judgments that, they have played crucial role in developing the concept of medical negligence and provided remedies to the patients. Allegation of malpractices and lack infrastructure in public hospitals have increased, while private service providers have been accused of profiteering and the exploitative practices. Weak regulation regime came in the way of redressal of grievances, most importantly such negligence matters are being verified by fellow doctors who hardly ever support the patient. There are many landmark decisions delivered by the judiciary such as Indian Medical Association case, Achutrao Haribhau Khodwa case, Jacob Mathew case, Anuradha Saha case etc. wherein court considered the various aspects of medical negligence to provide the remedy by imposing tortious, civil and criminal liability.

Medical negligence is the failure of a medical practitioner to provide proper care and attention and exercise those skills which a prudent, qualified person would do under similar circumstances. It is a commission or omission of an act by a medical professional which deviates from the accepted standards of practice of the medical community, leading to an injury to the patient. It may be defined as a lack of reasonable care and skill on the part of a medical professional with respect to the patient, be it his history taking, clinical examination, investigation, diagnosis, and treatment that has resulted in injury, death, or an unfavorable outcome. Failure to act in accordance with the medical standards in vogue and failure to exercise due care and diligence are generally deemed to constitute medical negligence.

Everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person. Negligence is not the act itself, but the fact which defines the character of the act, and makes it a legal wrong. In common law, negligence is a complex relationship, a space, more than a 'thing': a shifting, malleable, interaction between time and place and, to varying degrees, society, law, ethics, and professionals. The elements of a cause of action in tort of negligence are: (1) a duty to use ordinary care; (2) breach of that duty; (3) approximate causal connection between the negligent conduct and the resulting injury and (4) resulting damage. Negligence as a tort is the breach of a legal duty to take care, which results in damage undesired by the defendant, to the plaintiff.

In essence, negligence consists of failure to take reasonable precautions against risks of injury to others, which one ought to have foreseen and guarded against. Negligence involves behaving in a manner that lacks the legality of protecting other people against foreseeable risks. It is a Tort. Tort is a civil wrong committed by one person on another. The word 'Person' is the important issue in negligence. Fictional persons cannot be negligent though they may be held liable vicariously. In a negligence lawsuit the tortfeasor who committed the wrong is a person. Negligence in law is the failure to meet a standard of behavior established to protect society against unreasonable risk. It is the cornerstone of tort liability and a key factor in most personal injury and property's damage trials. The doctrine of negligence does not require the elimination of all risk from a person's conduct, only all unreasonable risk, are required to be eliminated, which is measured by the seriousness of possible consequences. Thus, a higher standard applies to nitroglycerin manufacturers than to those making kitchen matches. In certain critical fields, e.g. the milk industry, the law imposes liability for every mistake, even when the strictest precautions are taken, a policy known as strict liability. Car accidents are a common source of legal liability. In almost all accidents, someone will be found responsible for failing to act as they should. Most accidents result in damage to the vehicles or injury to people in them, and these are clearly a direct result of the accident. Negligence excludes wrongful intention since they are mutually exclusive. Carelessness is not culpable or a ground for legal liability except in those cases in which the law has imposed the duty of carefulness. Negligence may be in action or in omission.

Negligence is the omission to do something which a reasonable man, guided upon those considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do. The defendants might have been liable for negligence, if, unintentionally, they omitted to do that which a reasonable person would have done, or did that which a person taking reasonable precautions would not have done. A reasonable man would act with reference to the average circumstances of the temperature in ordinary years. The defendants had provided against such frosts as experience would have led men, acting prudently, to provide against; and they are not guilty of negligence, because their precautions proved insufficient against the effects of the extreme severity of the frost of 1856, which penetrated to a greater depth than any which ordinarily occurs south of the polar regions. Such a state of circumstances constitutes a contingency against which no reasonable man can provide. The result was an accident, for which the defendants cannot be held liable.

Supreme Court in its judgment simplified negligence as the breach of a legal duty to care. It means carelessness in a matter in which the law mandates carefulness. A breach of this duty gives a patient the right to initiate action against negligence.

The Hon'ble Apex Court admits that no human being is perfect and even the most renowned specialist could make a mistake in detecting or diagnosing the true nature of a disease. The law expects a duly qualified physician to use that degree of skill and care which an average man of his qualifications ought to have and does not expect him to bring the highest possible degree of skill in the treatment of his patients, or to be able to guarantee cure.

Thus as reflected from the various decisions of Supreme Court a doctor can be held liable for negligence only if -

1) One can prove that she/ he is guilty of a failure to act with ordinary skills and fail to act with reasonable care.[1]

2) An error of judgment constitutes negligence only if a reasonably competent professional with the standard skills that the defendant professes to have, and acting with ordinary care, would not have made the same error.[1]

3) The principle of res ipsa loquitur comes into operation only when there is proof that the occurrence was unexpected, that the accident could not have happened without negligence and lapses on the part of the doctor, and that the circumstances conclusively show that the doctor and not any other person was negligent.[1]

4) A doctor can be held to be negligent only if the complainant can prove that the standard of medical care given does not match the standards of care set up by the

profession itself. It says a wrong outcome or recourse to one of several different methods available to treat a patient cannot be termed as negligence.[2]

5) A simple lack of care, an error of judgment or an accident, even fatal, will not constitute culpable medical negligence. If the doctor had followed a practice acceptable to the medical profession at the relevant time, he or she cannot be held liable for negligence merely because a better alternative course or method of treatment was also available, or simply because a more skilled doctor would not have chosen to follow or resort to that practice. Professionals may certainly be held liable for negligence if they were not possessed of the requisite skill which they claimed, or if they did not exercise, with reasonable competence, the skill which they did possess.[3]

In legal sense medical negligence is a subset of professional negligence which is a branch of the general concept of negligence that applies to the situation in which physician who represented himself or herself having special knowledge and art, breaches his or her duty to take care about his or her patient. The general rules apply in establishing that the physician who owed the duty of care is in breach of that duty. Once the physician has accepted to treat the patient, the legal relationship between physician and patient is created, this means a medical relationship is established and this relationship resulted in duty to take care. The base of this legal relationship is the rule of 'reasonable reliance' by the claimant on the skills of the doctor. Dealing with the question of duty to take care, the court observed :

"Where a person is so placed that others could reasonably rely upon his judgment or his skill or upon his ability to make careful inquiry, and a person takes it upon himself to give information or advice to, or allows his information or advice to be passed on to, another person who, as he knows or should know, will place reliance upon it, then a duty of care will arise."

Under the Section 2(1)(o) of The Consumer Protection Act, 1986, the following categories of doctors/hospitals included under this Section and as interpreted by judiciary in different awards:

(i) All medical/dental practitioners doing independent medical/dental practice unless rendering only free service.

(ii) Private hospitals charging all patients.

(iii) All hospitals having free as well as paying patients and all the paying and free category patients receiving treatment in such hospitals.

(iv) Medical/dental practitioners and hospitals paid by an insurance firm for the treatment of a client or an employment for that of an employee. It exempts only those hospitals and the medical/ dental practitioners of such hospitals which offer free service to all patients.[4]

(v) A patient treated free of cost in a charity or other hospital will still be a consumer as per the Consumer Protection Act if the person buys medicines from the nursing home's pharmacy, the national consumer forum has ruled.[5]

(vi) Persons who availed themselves of the facility of medical treatment in a Government Hospital are not 'consumers' as defined in Consumer Protection Act and the said facility cannot be regarded as service "hired" for "consideration.[6]

(vii) It was contended that direct and indirect taxes paid to the State by a citizen constituted 'consideration' for the services and facility provided to a citizen by the State. The National Commission, making a distinction between 'tax' and 'fee' held that a tax is levied as part of common burden while fee is for payment of specific benefit or privilege. Unlike 'fee', 'tax' in its true nature is a levy made by the state for the general purposes of the Government and it cannot be regarded as payment for any particular or specific service.[6]

(viii) On the question whether contributors to the CGHS Scheme and patients in a 'paying ward' in a Government Hospital are 'consumers' within the meaning of the Act, it observed that contribution to CGHS should be taken to be in lieu of free treatment in the diverse dispensaries, as well as the free provisions of medicines from these dispensaries. In regard to 'paying wards', it further observed that these payments are specifically related to special rooms/beds for which the separate charge is made; the (free) medical facilities are common to all patients, inclusive of those in the paying wards, without discrimination.[6]

The famous Bolam principle states that a doctor cannot be held liable when he acted as any other

established and responsible medical man would act.[7] In a Jacob Matthews v State of Punjab,[8] the Hon'ble Supreme Court framed guidelines are as mentioned under :

I. A complaint against a doctor is not to be entertained unless the allegation against him is supported by a credible opinion given by another doctor. If the doctor feels that negligence on the part of the medical practitioner has resulted to the loss of well being of the plaintiff, then the complaint may be registered.

II. The investigating officer before proceeding against the accused ought to get a medical opinion from a competent doctor, preferably in the government services, qualified in that field of medical sciences who can give an impartial opinion.

III. The arrest of the accused should be withheld unless it is believed by the investigating officer unless he believes that it is necessary to arrest the accused so as to further the investigation of the case. It may further be withheld unless it is believed that the accused doctor will not make himself available to face the prosecution unless he is arrested.

As far as judiciary is concerned, it has considered various aspects of medical negligence and widened the meaning of it. In the very landmark judgment Indian Medical Association[9] case the supreme court defined the parameters of rights and obligations of professionals of allopathic and homeopathic systems of medicine and ruled that the Consumer Protection Act, 1986 is applicable to persons engaged in medical profession either as a private practitioner or as a Government doctor working in hospitals or Government dispensaries. It is further held that a patient who is a consumer within the meaning of the CP Act 1986, has to be awarded compensation for loss or injury suffered by him due to negligence of the doctor by applying the same tests are applied inaction for damages for negligence in law of torts. In the present case the issues before the court were , in what circumstances a medical practitioner can be regarded as rendering 'service' as per the definition given under CP Act 1986 and another issue was if the service rendered at a hospital or nursing home can it be comes under the definition of 'service' of CP Act 1986. The Supreme Court mentioned that medical service is treated as in ambit of 'services'. It is not contract of personal service as there is absence of master servant relationship. Further if the medical service is rendered free of charge are not in the purview of 'service'. On the other hand if such medical service is rendered by independent doctors free of charge are under the definition of service. Furthermore, medical service if rendered against payment of consideration is in the scope of the Consumer Protection Act, 1986. In addition to this court also mentioned that a medical service where payment of consideration is paid by third party is treated as in the ambit of the CP Act and also hospital in which some person are charged and some are exempted from charging because of their inability of affording such services will be treated as 'consumer' under the Consumer Protection Act, 1986. In another significant judgement the Supreme Court enlarged the ambit of vicarious liability and extended the reach of Consumer Protection Act, 1986. Chandrikabai, a teacher died on July 24, 1963 as the doctors had left a mop (towel) in her abdomen a sterilization operation in Aurangabad's Government hospital on July 10, 1963, where she was admitted for delivery. Court further mentioned that running a hospital could be a welfare activity by the Government but not sovereign function. Apex court held that once the death by negligence is established the doctrine of res ipsa loquitor i.e. things speaks for itself was held applicable in a case like this and the state as an employer would be liable to pay damages for negligence of the doctor. Theory of sovereign immunity has no application in such cases.

Negligence in the context of the medical profession necessarily calls for a treatment with a difference. To infer rashness or negligence on the part of a professional, in particular a doctor, additional considerations apply. A case of occupational negligence is different from one of professional negligence. A simple lack of care, an error of judgment or an accident, is not proof of negligence on the part of a medical professional. So long as a doctor follows a practice acceptable to the medical profession of that day, he cannot be held liable for negligence merely because a better alternative course or method of treatment was also available or simply because a more skilled doctor would not have chosen to follow or resort to that practice or procedure which the accused

followed.

When it comes to the failure of taking precautions, what has to be seen is whether those precautions were taken which the ordinary experience of men has found to be sufficient; a failure to use special or extraordinary precautions which might have prevented the particular happening cannot be the standard for judging the alleged negligence. So also, the standard of care, while assessing the practice as adopted, is judged in the light of knowledge available at the time of the incident, and not at the date of trial. Similarly, when the charge of negligence arises out of failure to use some particular equipment, the charge would fail if the equipment was not generally available at that particular time, at which it is suggested it should have been used.

The Hon'ble Supreme Court in Laxman v. Trimbak,[10] held:

"The duties which a doctor owes to his patient are clear. A person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties viz., a duty of care in deciding whether to undertake the case, a duty of care in deciding what treatment to give or a duty of care in the administration of that treatment. A breach of any of those duties gives a right of action for negligence to the patient. The practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. Neither the very highest nor very low degree of care and competence judged in the light of the particular circumstances of each case is what the law requires."

In Achutrao Haribhau Khodwa v. State of Maharashtra,[11] the Supreme Court said:

The skill of medical practitioners differs from doctor to doctor. The very nature of the profession is such that there may be more than one course of treatment which may be advisable for treating a patient. Courts would indeed be slow in attributing negligence on the part of a doctor if he has performed his duties to the best of his ability and with due care and caution. Medical opinion may differ with regard to the course of action to be taken by a doctor treating a patient, but as long as a doctor acts in a manner which is acceptable to the medical profession and the Court finds that he has attended on the patient with due care skill and diligence and if the patient still does not survive or suffers a permanent ailment, it would be difficult to hold the doctor to be guilty of negligence.

In a case Apex Court in Spring Meadows Hospital v. Harjol Ahluwalia,[12] has specifically laid down the following principles for holding doctors negligent:

"Gross medical mistake will always result in a finding of negligence. Use of wrong drug or wrong gas during the course of an anesthetic will frequently lead to the imposition of liability and in some situations even the principle of res ipsa loquitur can be applied. Even delegation of responsibility to another may amount to negligence in certain circumstances. A consultant could be negligent where he delegates the responsibility to his junior with the knowledge that the junior was incapable of performing of his duties properly. We are indicating these principles since in the case in hand certain arguments had been advanced in this regard, which will be dealt with while answering the question posed by us."

Recently Justice S.B.Sinha in Malay Kumar Ganguly v. Dr. Sukumar Mukherjee[13] case has preferred Bolitho test to Bolam test. The Supreme Court redefined medical negligence saying that the quality of care to be expected of a medical establishment should be in tune with and directly proportional to its reputation. The Court extended the ambit of medical negligence cases to include overdose of medicines, not informing patients about the side effects of drugs, not taking extra care in case of diseases having high mortality rate and hospitals not providing fundamental amenities to the patient. The decision also says that the court should take into account patient's legitimate expectations from the hospital or the concerned specialist doctor.

In V. Kishan Rao v. Nikhil Super Speciality Hospital,[14] the Hon'ble Supreme Court expressed the opinion that Bolam test needs to be reconsidered in India in view of Article 21, which guarantees right to medical treatment and care. However, the Court expressed its inability because of the binding precedent of Jacob Mathew, which approved the test.

In Kusum Sharma v. Batra Hospital and Medical

Research Centre,[15] the Hon'ble apex court reiterated the legal position after taking survey of catena of case law. In the context of issue pertaining to criminal liability of a medical practitioner, Hon'ble Mr. Justice Dalveer Bhandari speaking for the Bench, laid down that the prosecution of a medical practitioner would be liable to be quashed if the evidence on record does not project substratum enough to infer gross or excessive degree of negligence on his/her part.

In Vinitha Ashok v. Lakshmi Hospital,[16] removal of pregnancy was done without ultrasonography and uterus of the patient had to be removed. There was expert evidence to indicate that ultrasonography would not have established ectopic pregnancy but some text books indicated otherwise. The general practice in the area in which the doctor practiced was not to have ultrasonography done. Therefore no negligence was attributed on this ground even if two views could be possible.

In Dr. P.N. Rao v. G. Jayaprakasu, a very promising young boy of 17 was admitted in a government hospital for removal of tonsils. As a result of the negligence in the administration of anaesthesia during the operation, the patient became victim of cerebral anoxia making him dependant on his parents. The anesthetist, the surgeon and the government were all held liable for damages to the plaintiff.

In Nizam's Institute of Medical Sciences v. Prasanth S. Dhananka,[17] the complainant who was then an engineering student suffered from recurring fever. The X ray examination revealed a tumour in left hemithorax with erosion of ribs and vertebra. Even then without having MRI or Myelography done, cardiothoracic surgeon excised the tumour and found vertebral body eroded. Operation resulted in acute paraplegia of the complainant. MRI or Myelography at the pre-operation stage would have shown necessity of a nuerosurgeon at the time of operation and the paraplegia perhaps avoided. Consent was not taken for removal of tumour but only for excision biopsy. The hospital and the surgeon were held liable for negligence.

In Dr. Balram Prasad and others v. Dr. Kunal Saha and another,[18] Hon'ble Justice V. Gopala Gowda, and Hon'ble Justice C. K. Prasad, were pleased to pass an award of adequate and just compensation was finally decided by the Supreme Court on October 24, 2013, and it awarded a little more than Rs. 6 crores plus interest , which has been so far the highest compensation ever awarded by any court in India for medical negligence. Though the lawyers for the hospital and the doctors argued that the multiplier method should have been used for calculating compensation, the Supreme Court was clearly of the view that the method was not suitable for determining the quantum of compensation for medical negligence. The Hon'ble Supreme Court rejected the multiplier method in this case and provided an illustration to show how useless the method can be for medical negligence cases. The court wrote:

"The multiplier method was provided for convenience and speedy disposal of no fault motor accident cases. Therefore, obviously, a 'no fault' motor vehicle accident should not be compared with the case of death from medical negligence under any condition. The aforesaid approach in adopting the multiplier method to determine the just compensation would be damaging for society for the reason that the rules for using the multiplier method to the notional income of only Rs. 15,000/- per year would be taken as a multiplicand. In case, the victim has no income then a multiplier of 18 is the highest multiplier used under the provision of Ss. 163 A of the Motor Vehicles Act read with the Second Schedule.... Therefore, if a child, housewife or other non-working person fall victim to reckless medical treatment by wayward doctors, the maximum pecuniary damages that the unfortunate victim may collect would be only Rs.1.8 lakh. It is stated in view of the aforesaid reasons that in today's India, Hospitals, Nursing Homes and doctors make lakhs and crores of rupees on a regular basis. Under such scenario, allowing the multiplier method to be used to determine compensation in medical negligence cases would not have any deterrent effect on them for their medical negligence but in contrast, this would encourage more incidents of medical negligence in India bringing even greater danger for the society at large."

Thus, a doctor who is charged with negligence can absolve himself from liability if he can prove that he acted in accordance with the general and approved practice. He will be held liable only if the judgment is

so palpably wrong as to imply an absence of reasonable skill and care on his part.

The rules as to the duty of care in medical negligence cases are the same as the rules applicable to all other kinds of negligence. Common law recognizes four basic levels of fault: negligence, recklessness or wanton conduct, intentional misconduct, and strict liability (irrespective of fault). Negligence generally means careless or inadvertent conduct that results in harm or damage. It is a recurring factor in an aggregate majority of accidental damages. It encompasses both active and passive forms of fault. That is to say, failing or omitting to do something may result in liability just as much as actively doing something wrong. Reckless or wanton conduct generally refers to a willful disregard for whether harm may result and or a disregard for the safety and welfare of others. Strict liability may be imposed, even in the absence of fault, for accidents involving certain defective products or extra hazardous activities. In common law duty is the base of liability of a person to be punished, forced to compensate, or otherwise subjected to a sanction by the law. There are many grounds on which responsibility may be imposed, and others may be invented in the future, but those which have featured in legal systems up to now can be classified according to three criteria.

The first is the conduct of the person held responsible: is he responsible on account of his conduct, or is he held responsible irrespective of his conduct?

The second is causal connection. When a person is to be held responsible for harm, must it be shown that his conduct caused the harm? Or is it sufficient that he occasioned it, e.g. by providing an opportunity for the harm to be done? Or can he be held responsible in the absence of any such connection?

The third is fault. Can a person be held responsible only when he is shown to have been at fault or can he be held responsible even in the absence of fault, i.e. on the basis of strict liability?

Under civil law, at a point where the Consumer Protection Act ends, the law of torts takes over and protects the interests of patients. This applies even if medical professional provide free service. In cases where the services offered by the doctor or hospital do not fall in the ambit of 'service' as defined in the consumer Protection Act, patients can take recourse to the law relating to negligence under the law of torts and successfully claim compensation. The onus is on the patient to prove that the doctor was negligent and that the injury was a consequence of the doctor's negligence. Such cases of negligence may include transfusion of blood of incorrect blood groups, leaving a mop in the patient's abdomen after operating, unsuccessful sterilization resulting in the birth of a child, removal of organs without taking consent, operating on a patient without giving anesthesia, administering wrong medicine resulting in injury, etc

The Medical Negligence is a very hot topic now-a days in the Consumer Courts. The Profession of Medicine is getting worst with regards to the Supreme Court's decision and the whole aspect is turning its way to criminal prosecution which may hamper the prestige of medical profession. In recent time the cost of the medi-care has gone up enormously and beyond the reach of common man, the so-called cut-throat competition among the hospitals, notwithstanding. District and general hospitals have inadequate supply of medicines and medical equipment and the doctors there are working with no incentives. Provision of medical facilities through Government should be raised to a higher level by increasing the budget provisions for strengthening the government hospitals with equal facilities. Motive is something, which prompts a man to form an intention, and for the same the doctors must get an advantage as defense, because his major intention is saving life of the people. The doctors should also be more careful to perform their duties. Gross lack of competency or gross inattention, or indifference to the patient's safety can only initiate a proceeding against a doctor. A healthy medical environment can create a great society. Hence there should be a sense of responsibility in doctors as well as consumers regarding the standard care and knowledge (Doctor's) and regarding marinating the respect and prestige of doctor who save the life of human and are the sole base of saving humanity(Consumer's). Finally, most importantly the doctors individually and collectively shall introspect their style of functioning and make sincere attempt to strengthen doctor-patient relationship and strive to put forth in their best possible

care and skill and competence.

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Total Laryngectomy in Laryngeal and Hypopharyngeal Malignancy

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ABSTRACT

Introduction

Advanced laryngeal and hypopharyngeal malignancies are associated with significant morbidity and mortality for the patients with associated financial burden for the society. Recommended treatment for such malignancies includes total laryngectomy or total laryngectomy with partial pharyngectomy with or without neck dissection, radiotherapy (RT) alone or surgery followed by radio therapy and combined chemotherapy (CT) with radiotherapy (CCRT).

Materials and Methods

This retrospective study was conducted over a period of 5 years, in a tertiary care institute with aim to study the incidence of laryngeal and hypopharyngeal malignancy over a period of 5 years in a tertiary care institute, to assess the proportion of patients who agreed to undergo the proposed modality of treatment with surgery and post-operative radiotherapy, to note the post operative complications and also to assess the 5 year survival of the patients who completed the prescribed regimen.

Results

This study highlights the large gap between the high incidence of this disease (a total of 170 cases of laryngeal and hypopharyngeal malignancy diagnosed in our hospital over a five year period) and the low turnover of patients actually undergoing surgery for the same (8 out of 38 patients who were advised surgery underwent the same).

Discussion

Vast majority of laryngeal and hypopharyngeal malignancies are squamous cell carcinomas. Though 47 proved cases of hypopharyngeal malignancy and 36 proved cases of laryngeal malignancy were assessed, only 8 patients agreed to undergo surgery, indicating a large disparity between disease burden and treatment beneficiaries, despite an excellent 5 yr survival rate.

Conclusion

The results of this study emphasized the need for increased awareness regarding the favourable surgical outcome when associated with post-operative radiotherapy. A very high five year survival rate can be achieved by combined modality treatment. Late presentation and lack of awareness about the disease are significant hindrances for management of laryngeal and hypopharyngeal malignancy.

Keywords

Laryngectomy, Pharyngectomy, Radiotherapy.

Patients presenting with laryngeal or hypopharyngeal malignancy are usually in the elderly age group. Laryngeal malignancy represents one of the common head and neck malignancies accounting for approximately 20% of all head and neck malignancies. Though surgical treatment in selected patients with laryngeal and hypopharyngeal malignancy provides a fairly high chance of five year survival, unfortunately very few patients receive the appropriate treatment timely. The reason could be lack of awareness, fear of morbidity or financial constraints. Our study was done retrospectively over a period of 5 years in a tertiary care institute. The aim of the study was to evaluate the proportion of patients who agreed to undergo the proposed modality of treatment (total laryngectomy or total laryngectomy and partial pharyngectomy with or without neck dissection and post-operative radiotherapy); the post operative complications of the patients, who underwent surgery and their management; 5 year follow-up of patients who underwent total laryngectomy. This study also aimed to determine the five year survival and thus to have a

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better insight on the need to bring about awareness and motivation among those patients who could have had the advantage of survival with better quality of life.

Materials and Methods

Retrospective assessment of incidence of laryngeal and hypopharyngeal malignancy was conducted over a period of 5 years in a tertiary care hospital. Study was focused at evaluating the percentage of patients undergoing total laryngectomy (TL), treatment compliance of the patients, post operative complications and their management and follow-up of patients over the next five years.

Results

A total of 170 cases of laryngeal and hypopharyngeal malignancy were diagnosed clinically during the 5 years of study period. Out of these majority (96) had hypopharyngeal malignancy and the rest 74 had laryngeal carcinoma. But out of 96 hypopharyngeal malignancy patients only 47 turned up for admission and biopsy and out of 74 laryngeal carcinoma patients only 36 got admitted and biopsy was done.

Among the 47 patients with hypopharyngeal cancer 3 patients were in stage I and 3 in stage II , but majority were in stage IV(22 patients) and stage III(19 patients). Patients with advanced disease(6 patients) were not considered operable.

9 patients were subjected to radiotherapy while 10 patents were unfit for total laryngectomy due to other co-morbidities. Though remaining 22 patients were evaluated and considered fit for surgery, only 4 patients gave wilful consent for surgery and underwent Total Laryngectomy with partial pharyngectomy. 3 cases who were in stage III – T3 N0 M0 who underwent Total Laryngectomy (TL) with Partial Pharyngectomy(PP) and one patient in stage IV (T3 N2 M0) underwent TL with PP with ipsilateral Radical Neck Dissection (RND). All these 4 patients with hypopharyngeal carcinoma who consented for the surgery were subjected to total laryngectomy because in all the 4 cases patients had unilateral cord fixation and therefore organ preservation would not have subserved the purpose of functional preservation.Also we believe that the best treatment option for these economically backward patients is ideally the one with excellent locoregional control and which requires least follow-up and has less post treatment morbidities.

Out of the 36 patients diagnosed with laryngeal cancer, majority (20 patients) were in stage III, 8 patients were in stage IV, 6 patients in stage I and only 2 patients in stage II. 4 patients were diagnosed as having advanced disease. 8 were subjected to radiotherapy (RT), while another 8 were unfit due to other co-morbidities. Total laryngectomy was advised in 16 patients but only 4 patients consented for the curative surgery.

Out of the 4 cases, who have undergone Total laryngectomy, 3 were in stage III, of which 1 was supragalottic and 2 were glottic. One case was in stage IV (T3N1Mo). All the patients in our study who underwent curative surgery were males and in the age group between 36-68 years (mean age 56.80). Out of the 8 surgically treated patients, histophaological examination of 6 patients showed moderately differentiated, 1 each of well differentiated and poorly differentiated squamous carcinoma.

All the eight patients were referred for radiotherapy after wound healing. Six patients completed radiotherapy successfully while 1 patient discontinued it due to development of pharyngocutaneous fistula during RT. Another patient who refused to receive radiotherapy, developed recurrence after 2 yrs and died a year later. Speech rehabilitation was tried for the seven patients, out of which 5 successfully developed oesophageal speech.

Patients were followed up for 5 years- at the end of which 7 were alive with no recurrence.

Discussion

Larynx plays a fundamental role in human speech and communication. Vast majority of laryngeal and hypopharyngeal malignancies are squamous cell carcinomas.[1,2] Upto 40% of these patients present with advanced disease.[3] Advanced laryngeal lesions are associated with significant morbidity and mortality for the patient and increased financial burden for the

society[4,5].Management of advanced laryngeal carcinoma is complex and ideal strategy is debated.[6] Prevalent treatment for laryngeal malignancy included total laryngectomy (TL) with or without neck dissection, radiotherapy (RT) alone or total laryngectomy followed by radio therapy and combined chemotherapy (CT) with radiotherapy (CCRT).[6,7] In laryngeal malignancy, organ preservation strategies, either surgical or non surgical have dominated the treatment of early laryngeal malignancy in recent years.[8-11] Billroth is credited for performing the first TL in 1873, and for many years this has been the standard of treatment for advanced laryngeal carcinoma.[8,12] As combined non-surgical treatment modalities – RT, CT, CCRT, are integrated in the primary management of advanced head and neck cancer it became more apparent that organ preservation did not necessarily lead to function preservation. In other words simply preserving larynx does not guarantee its function.[11] Late functional compromise following CT/RT might involve voice as well as swallowing difficulties and on numerous occasions may necessitate a permanent tracheostomy and / gastrostomy. In fact quality of life in many individuals may end up to be much worse after organ preservation treatment compared to cases that have under gone TL and are able to normally and sufficiently communicate with aid of a prosthesis or other methods.[13]

In our study though 47 proved cases of hypopharyngeal malignancy were assessed for fitness for total laryngectomy, 22 patients were considered fit for surgery and only 4 patients agreed to undergo the surgery. This shows the reluctance of people to go for surgical management of the disease. Even those patients, who agreed for surgery, had stage III or IV disease. Greater awareness and health education may help in early diagnosis and rational management of hypopharyngeal and laryngeal malignancies. Three out of 4 patients in stage III underwent total laryngectomy with partial pharyngectomy. One case was in stage IV who underwent the above surgery along with ipsilateral radical neck dissection .

Out of 36 proved cases of laryngeal carcinoma 16 were advised total laryngectomy, out of which 4 patients agreed to undergo surgery. Three were in stage III; total laryngectomy was done. One patient was in stage IV; total laryngectomy with ipsilateral radical neck dissection was done. In all the cases who underwent Total laryngectomy (TL), Gluck Sorensen incision was used. For Radical Neck Dissection (RND), incision was extended superiorly and inferiorly. Once the larynx was delivered, pharynx was closed by T shaped repair in three layers; skin closed by interrupted sutures. Drain was removed on day 4. Stitches were removed on day 10. Oral feeding was started on day 12.

After total Laryngectomy following wound healing all 8 patients were referred for radiotherapy, 6 patients completed radiotherapy successfully while 1 patient discontinued it due to development of pharyngocutaneous fistula during radiotherapy. Another patient who refused to receive radiotherapy, developed recurrence after 2 years and died a year later.

Post-operative complications:

Two patients developed pharyngo-cutaneous fistula (PCF). One healed with conservative treatment. Second patient developed PCF during RT; he lived with it without any recurrence for over 5 years. Stomal stenosis was seen in one patient – widening / freshening of stomal edges was done and tracheostomy tube was inserted. One patient developed thyroid and parathyroid insufficiency - treated with supplements.. One patient, who refused RT, had recurrence - died a year later. Two patients with RND developed facial edema.

All 7 patients, who completed the treatment with surgery and post-operative radiotherapy, were alive with no recurrence at 5 years follow-up.

Conclusion

Though there is a very large turnout of laryngeal and hypopharyngeal malignancy patients at a tertiary care hospital, very few are willing for surgical intervention. The reason could be - unwillingness to accept deformity and loss of important function like speech. Financial constraint could be yet another factor. However, a large section of the patients diagnosed with malignancy were not fit to undergo surgery due to other co-morbidities or advanced stage of disease. But, if the patient is fit for surgery, curative surgical management with post-operative radiotherapy can give a good 5 year survival

rate. Therefore greater awareness among the general public and the referring doctor would enable early detection and better survival chances of those affected by the disease by providing necessary surgical intervention at a tertiary hospital like this, which largely caters to rural economically constrained population, thereby reducing the burden on referral oncology centres which are aleady overburdened.

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Kimura's Disease: A Rare Cause of Postauricular Swelling

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ABSTRACT

Introduction

Kimura's Disease is a chronic inflammatory disorder of lymph node which is very rare in Indian population.

Case Report

A 15 year old boy with multiple postauricular swelling for 18 months presenting in OPD and diagnosed having eosinophilia. Then excision biopsy was taken, which indicates Kimura's Disease. Patient was treated with high dose of corticosteroid.

Conclusion

Kimura's disease, though rare should be kept in mind for treating a patient with lymphadenopathy with eosinophilia or high IgE level, because it can spare the patient unnecessary invasive procedure.

Keywords

Kimura Disease; Eosinophilic Lymphadenitis; Lymphadenopathy

Kimura's disease is a rare, benign, chronic inflammatory disorder of unknown aetiology that involves lymph nodes and subcutaneous tissue of head and neck region. The condition is clinically characterized by triad of painless subcutaneous masses, blood and tissue eosinophilia and markedly increased serum IgE concentrations. The disorder is primarily seen in East Asian male patients in the third decade of life, though rare in Indian. Although it may mimic a neoplastic condition, early correct diagnosis of Kimura's disease may spare the patient from unnecessary invasive diagnostic procedure. We present such a case in a 15 year old boy who presented with bilateral postauricular swelling and focus on treatment modalities in our discussion.

Case Report

A 15 year old boy was referred to our outpatient department for workup for multiple bilateral postauricular subcutaneous swelling for 18 months. He was seen by his primary care physician who treated him with different types of oral antibiotics for many weeks. There was no history of fever, sore throat, cough, ear discharge or weight loss. Physical examinations showed an apparently well boy with multiple distinct palpable masses at the both postauricular areas which were non-tender, firm, non-fluctuant and freely mobile (Fig. 1). The largest discrete mass was 2.5 cm in diameter. The rest of the general physical and systemic examinations were normal.

Peripheral blood smear showed 11% eosinophils with absolute eosinophil count of 950/cumm. Chest radiograph was within normal limits. Tuberculosis skin test and rapid Infectious mononucleosis assay were negative.

Because of concern that the mass might be some lymphoproliferative disorder or neoplasm,an excision biopsy was taken. Histopathological examination of the mass showed eosinophilic infiltration and vascular proliferation with prominent endothelial cells within the extra nodal soft tissue associated with lymphoid hyperplasia and germinal centre formation. Serum IgE levels were estimated which showed - 5300 KIU/ml (Normal - 150 KIU/ml) further supported the diagnosis of Kimura's Disease.

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Fig.1. Postauricular swelling of a 15 year old boy

After 6 months follow up, the mass began to recur and then treatment with oral prednisolone was started at a dose of 40mg/day for the initial period of 6 week and subsequently tapered every week by 10 mg/day over next 4 weeks. After 4 weeks of treatment eosinophilia was decreased and became well within normal limits in 6 weeks. IgE levels fell to 144 KIU/ml gradually. There was no local recurrence at 9 months follow up.

Discussion

Kimura's Disease was first described by Kim and Szeto[1] in Chinese literature in 1937, but was later characterized by Kimura et al in 1948 in a manuscript titled "On the unusual granulation combined with hyperplastic changes of lymphatic tissue.[2] It is now recognized as a benign cause of painless localized lymphadenopathy of Asians, especially boys of Chinese and Japanese origin.[3] The clinical triad of subcutaneous nodule in head and neck region, prominent peripheral eosinophilia and highly elevated IgE, particularly when seen in an Asian male [in 2nd and 3rd decades of life, although can become apparent at any age] is highly suggestive of Kimura's Disease.

The clinical course of Kimura's Disease is benign and self-limited. The subcutaneous masses or adenopathy are usually found in head and neck region with occasional pruritus of overlying skin. It sometimes affects axillary, periauricular, inguinal or epitrochlear node.[4] Most patients have a prolonged course with slow enlargement of masses. Occasional spontaneous resolution is known. These lesions do not have any malignant potential. Kimura's Disease may be complicated by renal involvement. In case of renal involvement, nephrotic syndrome is the commonest presentation, proteinuria may occur in 12 - 16 % of cases.[5] But in our case, there was normal renal function and there was no evidence of proteinuria.

The pathophysiology of Kimura's Disease is not well understood at this time, but may relate to a disturbance in the normal rate of product of an interaction between types 1 and 2 helper cells. Such a derangement could result in excessive elaboration of eosinophilotrophic cytokines.[6] These patients have been shown to have high levels of circulating eosinophilic cationic protein and major basic protein with heavy concentration of IgE in their tissues.[7] Allergic or parasitic etiologies for Kimura's Disease have been actively sought, but not proven.

The pathology of Kimura's Disease is characterized by prominent germinal centres in involved lymph nodes containing cellular, vascular and fibrous components. The cellular component consists of dense eosinophilic infiltrate in background of abundant lymphocytes and plasma cells, eosinophilic micro-abscesses with central necrosis.[8,9] Other characteristics may include sclerosis, proteinaceous material and / or vascularity in the germinal centres and polykaryocytes of Warthin-Finkeldely type.[10]

The lesions can be further investigated with ultrasonography, CT scan and MRI. But their radiographic features are not pathognomonic. The diagnosis is made only by histopathological examination of excisional biopsy specimen of lesion.

The differential diagnosis of Kimura's Disease includes other entities such as Tuberculous adenitis, Mikulicz's Disease, Eosinophilic Granuloma, ALHE (Angiolymphoid Hyperplasia with Eosinophilia), Cylindroma, Pyogenic granuloma. It should also mimic some serious disorder like Hodgkin's Disease, Acute non-lymphocytic leukemia, follicular lymphoma

and Kaposi's sarcoma. Except for Angiolymphoid Hyperplasia with Eosinophilia, the clinical and histological features of these diseases easily distinguish them from Kimura's Disease.

There is no consensus on management of Kimura's Disease. Various treatment modalities have been tried with variable success. Three major therapeutic options exist for Kimura's Disease. Excision of the mass remains the treatment of choice if the entire lesion can be removed, but local recurrence is common. Localized initial regrowth can often be managed with repeated surgical excision. Local irradiation has occasionally been used to treat recurrent, persistent or refractory cases to surgical and medical therapy, recalcitrant and large lesions, young patient or when surgery is not feasible.[11] Finally, the pharmacotherapy of Kimura's Disease has mainly involved the use of systemic and intralesional corticosteroids for an adequate period have been shown to reduce the size of the lesion but the lesion tends to recur when the drugs are discontinued.[11,12] Cyclosporine, oral pentoxifylline, all trans retinoic acid with prednisolone, imatinib, leflunomide, azathioprine and vincristine have been tried in the management for Kimura's Disease with variable responses.[13]

The choice of treatment modalities should be individualized. Recurrence is common with all the modalities of treatment.

Our patient had excision of postauricular mass but after 6 months, recurrence of mass happened. Then the patient was treated with 1mg/kg/day of oral prednisolone for 6 weeks which allowed gradual regression of mass. The dose is then tapered over next 4 weeks.

Conclusion

Kimura's Disease may be suspected when eosinophilia or high IgE level are seen in a patient of slowly progressive head and neck swelling or lymphadenopathy.

If not properly diagnosed, the neck mass or postauricular mass may be initially mistaken for a malignancy leading to unnecessary and potentially invasive investigation. However due to a well-obtained clinical history and histological awareness a proper diagnosis has been established in our case.

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