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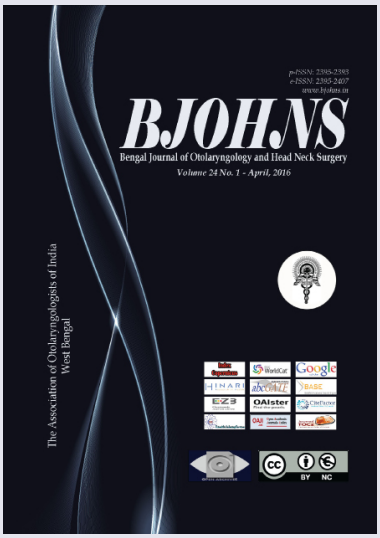

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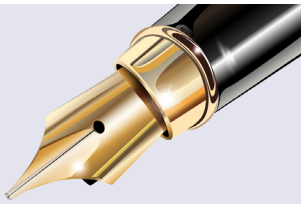
From the Desk of the Editor



Marcus Munafo, a biological psychologist at the University of Bristol, UK, as a student, tried to replicate some simple studies from literature, but failed. His confidence suffered a huge dent as a consequence. He started questioning and found that his experience was not uncommon.[1] Have you too not had a similar experience? Hasn't some surgical procedure or therapeutic protocol which was supposed to have a very good outcome failed to satisfy your expectations?

The idea that the same experiment will always produce the same result, no matter who performs it, is one of the cornerstones of science's claim to truth.[2] The reproducibility crisis gave rise to the suspicion that a lot of published research findings may be false.[3]

Nature's survey (2016) found that 'more than 70% of researchers have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments.'[1] Another study found that at least 50% of life science research cannot be replicated.[2] However, the exact extent of the malady is difficult to fathom. 'Forty four percent of scientists who have carried out an unsuccessful replication are unable to publish it.'[1]

Fabrication, falsification, plagiarism and cooking or mining of data (with the intention to deceive) are generally considered as scientific misconduct. Misconduct in clinical, pharmacological and medical research is more widespread than in other fields.[4] There is suspicion that large financial interests, that often drive medical research, are severely biasing it and may have serious implications on human health.[4]

The waste of financial resources is colossal; to the tune of US$ 28,000,000,000 per year on irreproducible pre-clinical research in the US alone.[5]

So why can't we trust the academic journals to tell the scientific truth? There is apprehension that academic journals might not select articles for publication on their scientific quality alone. The main reason for the spread of 'fake news' in scientific journals may be the tremendous pressure in the academic system to publish in the high-impact journals and such journals demand novel and surmising results to survive in the competitive market.[2]

Hwang Woo-Suk and Haruko Obokata's publications on stem cell research along with Yoshitaka Fujii and Joachim Boldt's research publications on anaethesiology shows how easy it is for a scientist to publish fabricated data in prestigious journals.

The scientific community must take an initiative now to restore faith in the outcome of scientific research and stop spread of fake news in academic publications. I agree with The Guardian when it said that it's time for academics to take back control of research journals.

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Dr Saumendra Nath Bandyopadhyay
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Radiological Analysis of Frontal Cells and its Association with Frontal Sinus Mucosal Disease: A Tertiary Care Hospital Based Study

Bikash Lal Shrestha,[1] Sameer Karmacharya[1]

ABSTRACT

Introduction

The frontal sinus and frontal recess both have complex anatomy causing difficulty during endoscopic sinus surgeries. The term frontal cells is currently used to describe a group of anterior ethmoidal cells classified by Kuhn et al into 4 types. Though there are precise descriptions, the frequency of frontal sinus cells (FSCs) varies widely in the literature. The presence of FSCs is responsible for a narrowing of the frontal sinus outflow tract which subsequently causes a partial obstruction of drainage and aeration of the frontal sinus. Our main aim is to the see the distribution of different frontal cells in Nepali population and relation with frontal sinus mucosal disease.

Materials and Methods

This prospective, longitudinal study performed in 110 consecutive patients who underwent CT scan of nose and paranasal sinuses. The frontal cells and agger nasi cells were identified and association between the frontal cells and agger nasi cells with frontal sinus mucosal disease was analyzed with chi square test.

Results

The agger nasi was present in 83.63% CT scans whereas frontal cells were distributed in 61.82% CT (computed tomogram) scans. There was not statistical significance and any association between the frontal cells and agger nasi cells with frontal sinus mucosal disease.

Conclusion

The frontal cells and agger nasi cells distribution in Nepalese population, even though in small sample size, is similar with other studies in the literature. There is also non association of either frontal cells or agger nasi cells with frontal sinus mucosal disease.

Keywords

Frontal Sinus; Tomography, X-Ray Computed; Frontal Cells

The frontal sinus and frontal recess both have complex anatomy causing surgeons difficulty during endoscopic sinus surgeries. So, pre-operative computed tomographic (CT) scan is mandatory to know the types of frontal cells and also other anatomic variations of paranasal sinuses.[1]

The frontal recess is basically an hour-glass structure through which the secretions of frontal sinus drain. Frontal sinus anatomy was first described by Schaeffer in 1916.[2] But Bent and Kuhn were the first to describe four distinct types of Frontal Sinus Cells (FSCs) in 1994.[3] The term frontal cells (frontoethmoidal cells) is currently used to describe a group of anterior ethmoidal cells that have been classified by Kuhn et al into 4 types.[3] Type I is a single frontal cell above an agger nasi cell. Type II is a group of cells in the frontal recess above the agger nasi. Type III is a pneumatized large cell from the frontal recess into the frontal sinus. Type IV is isolated cell inside frontal sinus. Frontal cells have been reported to occur in 20–41% of paranasal sinuses.[4] Though there are precise

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descriptions, the frequency of FSCs varies widely in the literature.[3,5,6] The variation could be explained by differences in patient population examined, or, perhaps, because of confusion surrounding nomenclature.[1]

The presence of FSCs is responsible for a narrowing of the frontal sinus outflow tract which subsequently causes a partial obstruction of drainage and aeration of the frontal sinus. Despite this, frontal sinus mucosal disease (as observed by mucosal thickening >3 mm) has only been previously associated in FSC types 3 and 4.[7]

Till now there had been no such study regarding analysis of different frontal cells in Nepali population. So our main aim is to the see the distribution of different frontal air cells in Nepali population and also relation with frontal sinus mucosal diseases.

Materials and Methods

This was the cross sectional study conducted in the Department of Otorhinolaryngology and Head and Neck Surgery, in a tertiary care teaching hospital in Nepal from 1st January 2018 to 30th April 2018. The ethical approval was taken from institutional review committee.

All patients aged 18 years and above who underwent Computed tomographic scans (CT Scan) of the nose and paranasal sinuses were included in the study whereas patient with previous sinus surgery, age <18 years, maxillofacial trauma, sinonasal malignancy, congenital anomaly and CT images of low resolution were excluded. Other types of frontal recess cells like inter frontal sinus septal cells, supraorbital cells, suprabullar cells, and frontal bulla cells were not included in this study.

110 consecutive patients who underwent CT scan of nose and paranasal sinuses and fits in the inclusion criteria were taken for the study.

CT scans were done in a 128 slice machine. Patient was positioned in supine position and using the parameters-130 kV, 145 mAs, and scan time of 3.5 seconds, a volumetric axial CT scan was taken with 3 mm slices thickness from the frontal sinus to the floor of maxillary sinus. Multiplanar reconstruction was done using 1 mm thin slices with 0.5 mm interval and images were obtained in all planes. The scans were studied to identify the different types of anatomical variations mainly identifying the agger nasi and the frontal cells as classified by Kuhn et al.[3] The cells were identified on the right and left sides separately on each side. Likewise, Lund - Mackay scoring system was used with score 0-2 for the frontal sinus mucosal disease. Score 0 – no opacity, 1 – partial opacity and 2 – total opacity.8 We have used score 1and 2 as mucosal disease.

For the statistical analysis, statistical package for social sciences version 23 (SPSS) was used.

Chi square test was used to analyze the statistical significance and association between agger nasi cells with frontal sinus mucosal disease and frontal cells with frontal sinus mucosal disease. Similarly, the frequency table was used to evaluate the frequency of gender, frontal cells and agger nasi cells. The p value of <.05 was taken as significant.

Results

There were total 110 CT scans included for the study. The age distribution was minimum 18 years to maximum 71 years with mean age of 54+/-14.44 years.

Regarding the gender distribution, both the male and female were equal in number (55 each).

Table I: The bilateral total distribution of frontal cells

TOTAL FRONTAL CELLS BILATERAL	FREQUENCY	PERCENT
Absent	84	38.18
type I	42	19.09
type II	38	17.27
type III	45	20.45
type IV	11	5
Total	220	100

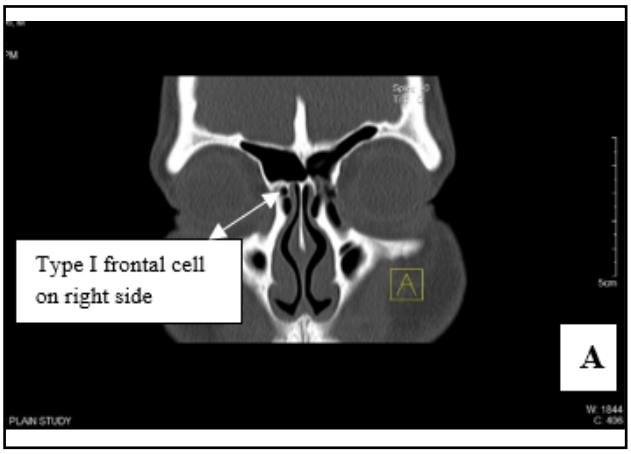

Fig.1. (A) Type I frontal cell on right side shown with arrow.

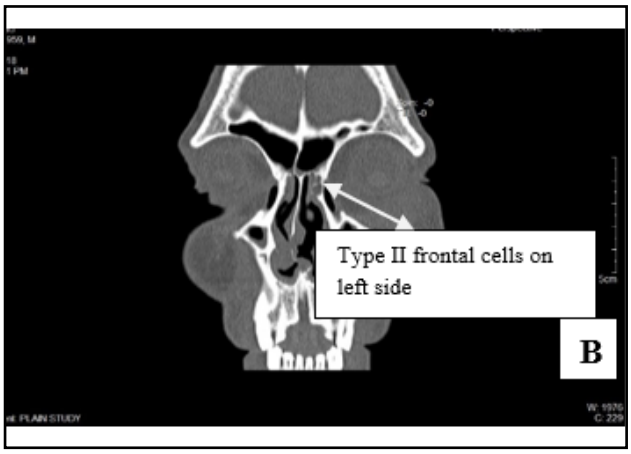

Fig.1. (B) Type II frontal cell on left side shown with arrow.

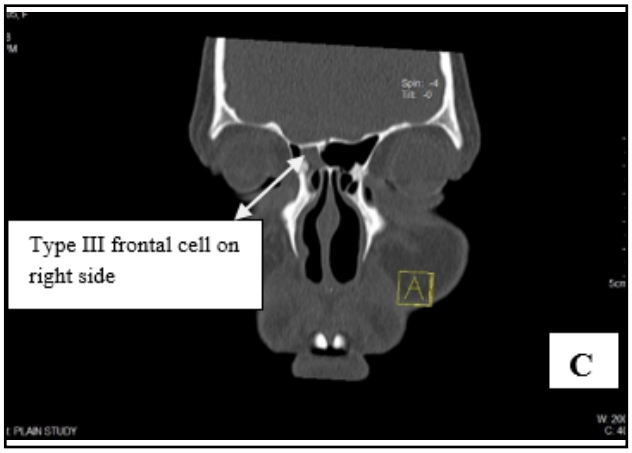

Fig.1. (C)Type III frontal cells on right side shown with arrow.

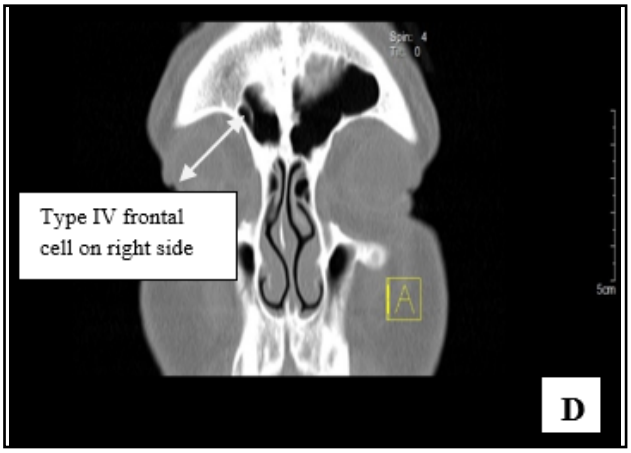

Fig.1. (D)Type IV frontal cells on right side shown with arrow.

The different types of frontal cells are as shown in Fig.1 A, B, C and D.

The bilateral distribution of frontal cells showed that it was present in 61.82% as shown in Table I.

Agger nasi cells were present in 83.63% as shown in Table II.

The Table III shows the cross tabulation between right frontal cells with right frontal sinus mucosal disease which was not statistically significant and also not associated.

Similarly, the Table IV showed the cross tabulation between left frontal cells with left frontal sinus mucosal disease which was not statistically significant and also not associated.

Table II: The distribution of agger nasi cells.

TOTAL AGGER NASI	FREQUENCY	PERCENT
Present	**184**	**83.63**
Absent	**36**	**16.36**
Total	**220**	**100**

Table III: Cross tabulation count between right frontal cells and right frontal sinus mucosal disease.

		FRONTAL SINUS MUCOSAL DISEASE RIGHT		TOTAL
		PRESENT	ABSENT	
Frontal cells Right	Absent	16	21	37
	type I	6	14	20
	type II	7	17	24
	type III	12	12	24
	type IV	1	4	5
Total		42	68	110

Table IV: Cross tabulation count between left frontal cells and left frontal sinus mucosal disease. (n=110)

		FRONTAL SINUS MUCOSAL DISEASE LEFT		TOTAL
		PRESENT	ABSENT	
Frontal cells Left	Absent	21	26	47
	type I	8	14	22
	type II	8	6	14
	type III	9	12	21
	type IV	0	6	6
Total		46	64	110

Chi-square test = 6.100; p=0.192; Non- significant

Linear by linear association = .838; p=0.360; Non-significant

Table V: Cross tabulation count between left agger nasi cells with left frontal sinus mucosal disease.

		FRONTAL SINUS MUCOSAL DISEASE LEFT		TOTAL
		PRESENT	ABSENT	
Agger Nasi Left	Present	37	53	90
	Absent	9	11	20
Total		46	64	110

Chi- square test = 0.102; p=0.750;Non-significant

Linear by linear association = 0.101; p=0.751; Non-significant

Table VI: Cross tabulation count between right agger nasi cells with right frontal sinus mucosal disease.

		FRONTAL SINUS MUCOSAL DISEASE RIGHT		TOTAL
		PRESENT	ABSENT	
Agger Nasi Right	Present	34	60	94
	Absent	8	8	16
Total		42	68	110

Chi- square test = 1.108; p=0.293; Non-significant

Linear by linear association = 1.098; p=0.295; Non-significant

Likewise, the Tables V and VI showed the cross tabulation between left agger nasi with left frontal sinus mucosal disease and right agger nasi with right frontal sinus mucosal disease and there was not any association and statistical significance.

Discussion

The frontal recess is a complex anatomical space that resembles an inverted cone, with the apex directed towards the frontal ostium. The frontal isthmus is filled by various anterior ethmoid or frontal recess cells.[3] The complex anatomy makes this space mandatory for comprehensive knowledge of frontal recess anatomy prior to surgery. The different views of CT scan (axial, coronal and sagittal views) make it easier to know the detail knowledge of frontal recess anatomy.

Our study showed that the frequency of agger nasi was 83.63% which is comparable with other studies in the literature which showed the prevalence of agger nasi

cells ranges from 52.87% to 94.1% respectively.[5,8-12] This shows the variation in pneumatisation of agger nasi cells in different population and different races.

The frequency of frontal cells in our study was 61.82% which is similar to study performed by Eweiss et al.[13] which showed the frequency of frontal cells around 78.57%. But this is higher than the other studies which showed the prevalence of frontal cells ranges from 20-41% respectively.[7,14,15] The reason behind such high frequency of frontal cells could be different variation of races within our community and we had also included cells as frontal cells as named by Kuhn et al.[3]

Regarding the distribution of frontal cells, our study showed that the type I frontal cells 19.09%, type II 17.27%, type III 20.45% and type IV 5%. Other studies also showed the marked variation of different frontal cells with type I cells were found in 13.6–28% of sinuses, type II cells were found in 2–14%, type III cells were found in 1.9–11%,and type IV cells were found in 0–3.1%.[4,6,9-11,16,17] The type III cells are somehow higher in our study, the reason could be because of different variation races in our community from Mongols to Aryans.

Regarding association of frontal sinus mucosal disease with agger nasi cells and frontal cells, our study showed no significant association which is similar to other studies.[4,13] However, another study showed an association between FSCs and frontal mucosal thickening only to be statistically significant in type 3 and type 4 cells.[7]

The reason behind our study could be apart from the anatomic variations in the frontal recess causing frontal sinus pathology, mucosal inflammation are also possible etiology.[4,18] Seven major factors were explained in literature as associated with frontal sinus pathology and they are: mucosal disease (67 %); presence of ethmoid cells (53 %); lateralization of middle turbinates (30 %); presence of agger nasi cells (13 %); scar tissue (12 %); presence of frontal cells (8 %); and neo-osteogenesis (7 %), with most frontal recesses having more than one factor (average 1.6).[19] These could be the reason for non-association of frontal sinus mucosal disease with frontal cells or agger nasi cells in our study.

This is the first time we are exploring the agger nasi and frontal cell types in Nepali population, even in small group, and also association with frontal sinus mucosal disease. So, we are somehow able to find the variation in frontal cells and agger nasi cells and association with frontal sinus mucosal disease in Nepali population, even though it is in small sample size. This is quiet new in Nepali population as these sort of study not done in Nepal previously.

The major limitation of the study is we had not included all frontal cell system for the analysis of frontal sinus disease. Moreover it will be more reliable if we analyze the different frontal cells with clinical and radiological findings. The further study in large sample size of population is required to know the distribution of frontal cells and also association with frontal sinusitis using both clinical and radiological criteria. Probably this will fulfill with multicentric study within different institutions of Nepal.

Conclusion

This is the first study on the distribution of the he frontal cells and agger nasi cells in Nepalese population. Even though the sample size is small, the incidence has been found to be similar with other studies in the literature. There is also non association of either frontal cells or agger nasi cells with frontal sinus mucosal disease.

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Mucormycosis: Effect of Comorbidities and Repeated Debridement on the Outcome

Harshavardhan N Reddy,[1] Sanjay B Patil, [1] Chandrakiran Channegowda, [1] Aiswarya Muralidharan, [1]

ABSTRACT

Introduction

Mucormycosis is an aggressive, invasive infection caused by ubiquitous filamentous fungibelonging to the subphylum Mucormycotina, order Mucorales. Mucormycosis most commonly affects immunocompromised hosts, but are rarely reported in immunocompetent hosts as well. The most common reported sites of invasive mucormycosis have been the sinuses (39%), lungs (24%), and skin (19%). The hallmark of mucormycosis is angioinvasion resulting in vessel thrombosis and hence, tissue necrosis.

Materials and Methods

Ambispective study of 20 cases with mucormycosis seen and treated in our hospital between 2009 and 2015 and followed up to 2017 to compare the prognosis of the cases of repeated debridement with that of single debridement and effect of comorbidities in the outcome of patients mortality .

Results

Out of 20 patients 19 (95%) received Liposomal Amphotericin B. 11 (55%) were male and 9 (45%) were female. All the 7 (35%) who underwent repeated debridement survived. Out of 13 (65%) patients who underwent single debridement, 5 (25%) did not survive. 2 (10%) patients were lost for follow up. The survival amongst the patients undergoing multiple debridement and single debridement was statistically significant (p=0.042)

Conclusion

The chances of survival are better in cases with better controlled comorbid conditions like diabetes mellitus. Repeated debridement with Liposomal Amphotericin B is the most effective mode of management..

Keywords

Mucormycosis; Comorbidity; Amphotericin B; Debridement

Mucormycosis is an aggressive, invasive infection caused by ubiquitous filamentous fungi belonging to the subphylum Mucormycotina, order Mucorales, which grow in soil and dead and decaying matter. Fungi belonging to this order are further divided into 6 families, all of which can cause cutaneous and deep infections. Species belonging to the family Mucoraceae are most often responsible for mucormycosis and among them, Rhizopus species is by far the most common cause of infection followed by Mucor and Lichtheimia species.[1]

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Mucormycosis most commonly affects immunocompromised hosts, but has rarely been reported in immunocompetent hosts as well. It infects people with haematological malignancies, on cancer chemotherapy, organ transplant, uncontrolled diabetes, patients on deferoxamine therapy in iron overload following dialysis. It has been observed that trauma patients also develop mucormycosis as wounds get contaminated with the fungus.[2]

Mucormycosis is an emerging problem of the developing world and more recently, even in the developed countries. Owing to the rising prevalence of diabetes, cancer, and organ transplantation in the ageing population, the number of patients at risk for this deadly infection is expected to continue to rise.[3]

The main principles of treatment are early diagnosis, correction or control of the associated comorbidities, surgical debridement of infected tissue and adequate and appropriate antifungal therapy.[1]

Materials and Methods

Ambispective study of patients who were diagnosed and treated at our centre from Jan 2009 to Dec 2015. Data was assessed regarding age, sex, presenting symptoms, orbital involvement, comorbidities and management.

Results

Our study included 20 patients, out of which 11 (55%) were males and 9 (45%) were females. Age ranged from 10 years to 65 years with a mean age of 41.05 years. 18 (90%) of the patients had associated comorbidities. Of the other 2 (10%) without comorbidities, one 65 year old patient with isolated sphenoid sinus involvement and a 15 year old boy who presented with extensive involvement with cavernous sinus thrombosis.

13 (65%) patients had uncontrolled Diabetes Mellitus and a total of 6 (30%) patients had Chronic Kidney Disease. Out of 13 patients with Diabetes Mellitus, 3 had Chronic Kidney Disease. Out of these 13 patients with Diabetes Mellitus, 5 (38%) survived after adequate control of blood sugars, extensive debridement and liposomal Amphotericin B and 2 (15%) were lost to follow up. 13 (65%) patients had orbital involvement. Out of this 13 with orbital involvement, 5 (38.4%) patients underwent orbital exenteration and remaining 8 (61.5%) underwent orbital decompression (Table I).

A total of 5 (25%) patients succumbed to the disease and a total of 2 (10%) patients were lost to follow up. 7 (35%) patients underwent repeated debridement. All the patients who underwent repeated debridement survived the disease. Of the 5 (25%) patients who succumbed to the disease, 3 (15%) patients had orbital involvement.

After suspicion of Sino nasal mucormycosis, patients underwent biopsy. Tissue was sent for both KOH mount and culture. After the initial report was suggestive of fungal hyphae, patients were started on intravenous Liposomal Amphotericin B, if the serum creatinine was within normal limits. All but one patient (19 (95%)) received Liposomal Amphotericin B ranging from 100 mg to 4.3 gms. The only patient who did not receive Amphotericin B was case 1, who could not afford it and expired on 2nd day post-op. Initial dose varied from 50 milligrams to 200 milligrams, depending on the serum creatinine and disease load. Patients with orbital involvement and intracranial extension received up to 200 mg and others were started on 50 mg.

All the patients were put in the ICU and remained there as long as they received Liposomal Amphotericin B. Patients were taken up for endoscopic debridement within the next 24 hours. Extensive debridement of the involved mucosa and tissue were debrided, till fresh bleeding normal tissue was encountered. All the tissue was again sent for histopathology and KOH mount. Patients were examined with nasal endoscopy in the OPD on every day and upon finding further tissue involvement, repeated endoscopic debridement was done in the operation theatre.

Repeated debridement was planned based on clinical findings of further progress of disease like palatal discolouration, worsening of orbital swelling etc. and repeat endoscopy in OPD (only if the patient is stable enough to be shifted to OPD). If any clinical sign of disease progress or endoscopic findings of further tissue necrosis was identified, then further debridement was done in OT.

No radiological investigations were undertaken in deciding repeated debridement. Orbital decompression or exenteration was done based on whether orbit was oedematous or involved. Orbit involvement with no vision was a prerequisite for orbital exenteration. Orbital exenteration was done by Ophthalmologists. Patient continued to receive Liposomal Amphotericin B till they were completely disease free or till they developed toxicity. Serum creatinine was monitored daily and if the value was deranged, Liposomal Amphotericin B was withheld till the values returned to normal (Table I).

Patients were followed up to a period of two years and endoscopic examination was done in the OPD during each review. Initially patient was reviewed every 2 weeks for 1 month, then monthly for 6 months and subsequently every 6 months up to 2 years.

Table I: Details of the cases including management and survival

SL NO	AGE/SEX	ORBIT INVOLVED	CO MORBIDITIES #	SURGICAL MANAGEMENT *	AMPHOTERICIN B (TOTAL DOSE)	SURVIVAL @
1	65/F	Yes	DM	DO, OE	NIL	x
2	28/F	No	CKD	DO	200 mg	+
3	48/M	No	CKD	DO	200 mg	+
4	55/F	Yes	DM	DR, OD	1.3 gm	+
5	65/M	No	NIL	DO	1.3gm	+
6	45/M	Yes	DM	DR, OD	1.2gm	+
7	10/M	Yes	Ac. Lymp. Leuk.	DO, OD	200 mg	+
8	65/M	No	Rec, CKD, DM	DO	1.0 gm	x
9	15/M	Yes, CST	NIL	DO, OE	150 mg	x
10	16/F	Yes	PVF (Dengue) -1 week	DR, OE	2.5 gm	+
11	45/M	No	DM	DO	150mg	x
12	33/M	No	CKD, Post Renal Transplant	DO	100mg	+
13	50/M	Yes	DM	DO, OE	1.5 gm	+
14	40/M	Yes	DM, CKD	DO, OD	50 mg	--

Table I: Details of the cases including management and survival

SL NO	AGE/SEX	ORBIT INVOLVED	CO MORBIDITIES #	SURGICAL MANAGEMENT *	AMPHOTERICIN B (TOTAL DOSE)	SURVIVAL @
15	45/F	No	DM	DO	100mg	--
16	62/F	Yes	DM, CKD	DO, OD	250 mg	x
17	32/F	Yes	DM, PVF & TCP	DR, OE	4.3gm	+
18	34/F	Yes	DM	DR, OD & RM	1.3gm	+
19	33/M	Yes	DM	DR, OD	2.0 gm	+
20	35/F	Yes	DM	DR, OD	2.0 gm	+

Abbreviations:

 # (DM = Diabetes Mellitus, CKD = Chronic Kidney Disease, Ac. Lymp. Leuk. = Acute Lymphoytic Leukemia, CST = Cavernous Sinus Thrombosis, PVF = Post Viral Fever, TCP = Thrombocytopenia, Rec = Recurrence of mucormycosis).

** (DO = Debridement Once, DR = Debridement Repeated, OE = Orbital Exenteration, OD = Orbital Decompression, RM= Radical Maxillectomy).*

@ (survived = +, not survived = x, lost for follow up = --)

Discussion

Mucormycosis is an emerging problem of the developing world and more recently, even in the developed countries. Owing to the rising prevalence of diabetes, cancer, and organ transplantation in the ageing population, the number of patients at risk for this deadly infection is expected to continue to rise.[3]

There has been an increasing incidence of Diabetes Mellitus and Cancer in the elderly population which translates to an increase in the incidence of mucormycosis. The initial symptoms of Rhinocerebral mucormycosis are vague and present similar to sinusitis and periorbital cellulitis[1] and include eye or facial pain and facial numbness, followed by the onset of conjunctival suffusion, blurry vision, and soft tissue swelling. If undetected and left untreated in the early stages, the infection spreads from the paranasal sinuses into the orbit and this could affect the function of the extraocular muscles. Upon visual inspection, infected tissue may appear normal during the earliest stages of spread of the fungus. Infected tissue then progresses through an erythematous phase, with or without edema, before onset of a violaceous appearance, and finally the development of a black, necrotic eschar (Figs. 1 & 2) as the blood vessels become thrombosed and tissue infarction occurs.[4] Further involvement of the orbit causes proptosis and progressive vision loss. This could

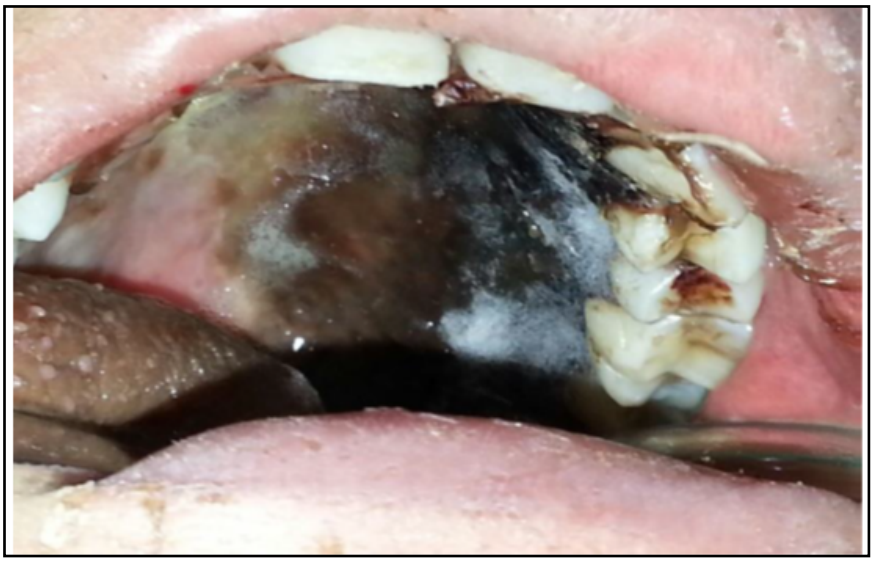

Fig. 1. Mucormycosis in a 15 year old boy with palatal involvement with eschar of palate.

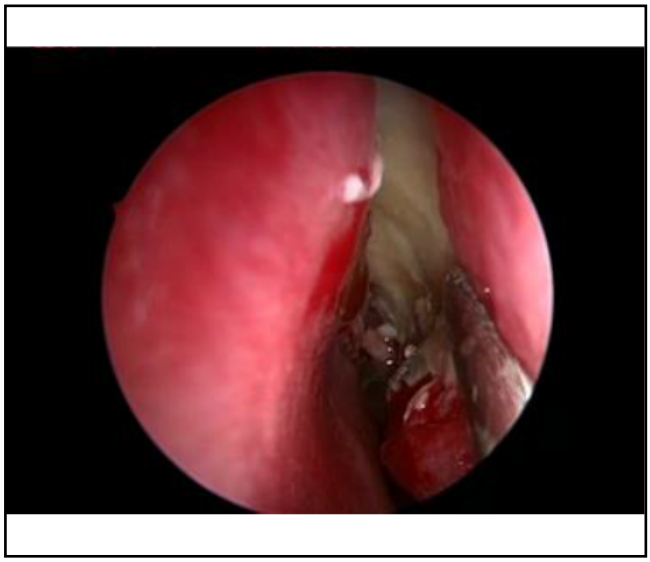

Fig. 2. Mucormycosis involving the left lateral nasal wall in a 16 year old patient recovering from Dengue fever

Fig. 3. Post treatment Diagnostic Nasal Endoscopy of the patient in Fig 2 (OPD Review).

be due to direct involvement of the optic nerve or due to thrombosis of the vessels supplying the nerve or because of cavernous sinus thrombosis. The infection can further extend superiorly and posteriorly into the cranial cavity.

The most common reported sites of invasive mucormycosis have been the sinuses (39%), lungs (24%), and skin (19%).[3] The hallmark of mucormycosis is angioinvasion resulting in vessel thrombosis and hence, tissue necrosis. This ability of angioinvasion by the fungus causes the fungus to disseminate haematogenously from the site of origin to other areas.

The main principles of treatment are early diagnosis, correction or control of the associated comorbidities, surgical debridement of infected tissue and adequate and

appropriate antifungal therapy.[1] Early and rapid diagnosis is achieved by a detailed endoscopic evaluation of the nasal cavity. Radiographic evaluation is not diagnostic, but aids to ascertain the extent of the disease and to substantiate diagnosis. Contrast Enhanced Computed Tomography of the Paranasal Sinuses shows mucosal thickening, periorbital thickening and erosion of bone margins. Magnetic resonance (MR) imaging is quite useful in identifying the intradural and intracranial extent of rhino-orbito-cerebral mucormycosis, cavernous sinus thrombosis, and thrombosis of cavernous portions of the internal carotid artery. Contrast-enhanced MR imaging can also demonstrate perineural spread of the infection.[5] This devitalized mucosa appears on contrast-enhanced MR imaging as contiguous foci of non-enhancing tissue.[6]

Diagnosis is confirmed by histopathological examination. Stains like hematoxylin and eosin, Grocott-Gomori methenamine–silver nitrate, and periodic acid-Schiff, reveal characteristic hyphal elements in tissue. Histopathologic examination reveals characteristic broad (3-25 μm in diameter), ribbon-like, thin-walled, aseptate hyphae that have irregular diameters; with nondichotomous irregular branching and accompanying tissue necrosis and fungal angioinvasion. Improved staining procedures with fluorescent stains, such as Calcofluour White, may be more revealing with small numbers of hyphae or limited tissue samples. Even the presence of fungal hyphae in histopathologic analysis, fungal cultures are only positive in 50% of cases because of the friable nature of nonseptate hyphae, which are frequently damaged during tissue manipulation.[7]

Pathogenesis research has led to the possibility of using Mucorales-specific T cells as a potential diagnostic test for mucormycosis.[2]

The only two systemic anti fungals with good activity against Mucorales are Amphotericin B and Posaconazole. Reed et al, in a retrospective analysis of diabetic patients with rhino-orbital-cerebral mucormycosis, noted that patients who received combination lipid amphotericin B-caspofungin therapy had significantly better treatment success and survival time compared with patients who received amphotericin B monotherapy.[8]

Patients who respond to a parenteral amphotericin B-based treatment, given for at least 3 weeks, are then switched over to oral Posaconazole as maintenance therapy. Amphotericin B has the ability to produce prolonged tissue concentration and hence maintenance therapy using 5mg/kg 2-3 times a week after initial therapy can be used instead of Posaconazole.[7]

For potential novel therapies, passive immunization targeting virulence genes of Mucorales such as iron acquisition through high affinity iron permease or proteins involved in mediating host cell invasion has proven to be effective against experimental mucormycosis.[2] Equally important, research into the immunopathogenesis of mucormycosis likely will pave the road for new treatment modalities that include adoptive immunotherapy using Mucorales-specific T cells and/or NK cells.

Aggressive antifungal therapy and extensive and sometimes even disfiguring debridement of the infected tissues is the treatment of choice and despite this, the mortality is about 40% or more.

The study conducted at our centre, included 20 patients with a confirmed diagnosis of Mucormycosis. 19 (95%) received Liposomal Amphotericin B, only 1 patient did not recieve Amphotericin B due to financial constraints and he succumbed to the disease. Out of the 20 patients, 2 (10%) patients did not have any known comorbidities, a 65 year old patient with isolated sphenoid sinus involvement and a 15 year old boy who presented with extensive involvement with cavernous sinus thrombosis. Out of 18 (90%) who had complete follow up 16 (80%) patients had co morbidities, out of which 13 (65%) patients had Diabetes Mellitus, 6 (30%) patients had Chronic Kidney disease and 3 (15%) patients had both Type 2 Diabetes Mellitus and Chronic Kidney Disease. 1 (5%) patient had Acute Lymphocytic Leukemia and 1 (5%) patient was recovering from Dengue fever (Fig 2 and 3). Diabetes Mellitus is the most common comorbidity seen in 65% cases (Table I).

Out of the 20 patients, 13 (65%) patients had orbital involvement of which 8 (61%) patients underwent Orbital Decompression and 5 (38%) patients underwent Orbital Exenteration. A total of 5 (25%) patients succumbed to the disease and a total of 2 (10%) patients were lost to follow up. All the 7 (35%) patients who

underwent repeated debridement survived (100%), while out of the 13 (65%) who underwent single debridement, 2 were lost to follow up and of the 11 (55%) who were followed up only 6 (54.5%) survived. As per Chi Square test differences in the survival rate with multiple debridement and single debridement amongst the comorbidities was found to be statistically significant (p=0.042)

Of the 5 (25%) patients who succumbed to the disease, 3 (15%) patients had orbital involvement, 4 (20%) of them had uncontrolled Diabetes Mellitus and 2 (10%) had both (Table I).

The above results indicate the importance of control of blood sugar levels in patients with Mucormycosis. The chance of survival is better in cases in which the comorbid conditions are controlled better. Our study shows that repeated debridement with Liposomal Amphotericin B is the most effective mode of management, especially in Orbital involvement. Due to small sample size individual morbidities were not considered.

After the initial surgery, patient has to be reassessed every day in the OPD with diagnostic nasal endoscopy (Fig. 3) and if tissue is found to be unhealthy, then further debridement has to be carried out at the earliest. Rigid control of the diabetes along with Liposomal Amphotericin B is very important in controlling the spread of the disease. Only drawback is ICU set up is needed for these patients to receive Amphotericin B, due to the toxicity of Amphotericin, so it may not be possible to undertake these measures in a rural set up.

Conclusion

The initial study suggests that repeated debridement give a better prognosis compared with single debridement along with Liposomal Amphotericin B in all cases. Proper control of co-morbidities ensures a better outcome. Larger sample studies with appropriate randomisation is warranted to generate clinical evidence in this regard.

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A Comparative Study of Outcomes of Type I Tympanoplasty with or without Fibrin Glue

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ABSTRACT

Introduction

Various materials have been used in tympanoplasty to ensure the adherence of the graft with the remnant tympanic membrane. This study aims to compare the clinical outcomes of type I tympanoplasty done with and without fibrin glue.

Materials and Methods

This is a prospective comparative study conducted in a tertiary care centre between August 2014 and July 2016. A sample size of 70 patients was used. The patients were randomly divided into two groups – Group A and Group B. Patients in group A underwent tympanoplasty with fibrin glue and patients in group B underwent tympanoplasty without fibrin glue. The patients were followed up for 6 months and the postoperative hearing improvement and graft uptake rates were compared.

Results

The pre-operative mean pure tone average for group A was 34.33±7.3dB; it improved to 22.14±6.5 at the end of 6 months. In group B, it improved from 34.25±8dB to 22.64±7.4dB at the end of 6 months. There was no statistical significance in hearing improvement between both the groups. Though there was no statistically significant difference in the graft uptake rates between group A (94.3%) and group B (91.4%), fibrin glue had better outcomes with larger perforations.

Conclusion

The use of fibrin glue in tympanoplasty is safe and it has a particular advantage in the graft uptake in subtotal perforations..

Keywords

Tympanoplasty; Fibrin Tissue Adhesive

Chronic Otitis Media – mucosal type is defined as the chronic inflammation of the middle ear cleft in the presence of a persistent tympanic membrane perforation. It is also known as 'safe' ear as life-threatening complications are rare as compared to squamous disease ('unsafe' ear). The treatment of chronic otitis media focuses on the mucosal inflammation in the tympanomastoid compartment. When we are certain that a chronic discharging ear cannot be cured by conservative treatment and have ruled out tubal discharge resulting from nasopharyngeal or sinus suppuration or from allergies, reconstructive middle ear surgery is indicated.[1]

Type I tympanoplasty through a post-aural approach with temporalis fascia is a commonly done procedure. Based on their preference, surgeons employ various techniques like underlay, overlay or inlay. Different materials are also used to ensure the adherence of the graft with the remnant tympanic membrane. The use of fibrin glue is being explored for various otorhinolaryngology procedures, especially in otological surgeries like tympanoplasty.

We have studied the use of fibrin glue (two component fibrin sealant) in type I tympanoplasty and compared it with conventional methods by assessing the audiological outcomes and the graft up-take rates.

Materials and Methods

This is a prospective comparative study done in the ENT

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department of a tertiary care hospital from August 2014 to July 2016. A sample size of 70 patients was randomly divided into two groups – Group A and Group B, using RAS software. All surgeries were performed by a single surgeon. Patients undergoing type I tympanoplasty for chronic otitis media – mucosal type with a dry ear for at least 4 weeks were included in the study. Patients with a sensorineural hearing loss or a conductive hearing loss more than 45 dB were excluded from the study. Patients undergoing revision surgeries were also not included in the study.

The patients selected as per the inclusion and exclusion criteria were subjected to a detailed history and clinical examination. Otomicroscopy, pure tone audiometry and posterior rhinoscopy were done preoperatively. The size of the tympanic perforation was noted and based on the number of quadrants involved and were divided into small, medium, subtotal and total perforations.[2] A written informed consent was obtained from the patient.

The surgery was done under general anaesthesia. As a standard, temporalis fascia graft was harvested by post-aural route and was used in the repair of the perforation. The procedure was done under the vision of an operating microscope.

- In Group A, fibrin glue is applied along the edges of the perforation.
- In Group B, fibrin glue is not applied.

Following the procedure, the external auditory canal was packed with gelfoam and the postaural wound was closed in layers with 3-0 vicryl (Polyglactin 910) and 3-0 ethilon (monofilament nylon) following which sterile dressing was applied.

The patients were followed up for 6 months. Postoperatively, the graft uptake was assessed at the end of one month, three months and six months. Pure tone audiometry was done postoperatively at three and six months.

Results

A total of seventy patients were included in the study who underwent type I tympanoplasty between August, 2014 and July, 2016. They were randomly divided into two groups. In one group fibrin glue was used (Group A) and in the other group fibrin glue was not used (Group B).

There were 10 right ears and 25 left ears in group A and there were 11 right ears and 24 left ears in group B. There was no statistically significant difference between the two groups.

In group A, there were 11 subtotal perforations, 7 involving the antero-inferior and antero-superior quadrants, 5 involving the antero-inferior and postero-inferior quadrants, 4 involving the postero-superior and postero-inferior quadrants, 5 involving the antero-inferior quadrant alone and 3 involving the postero-inferior quadrant alone.

In group B, there were 11 subtotal perforations, 2 involving the antero-inferior and antero-superior quadrants, 7 involving the antero-inferior and postero-inferior quadrants, 4 involving the postero-superior and postero-inferior quadrants, 7 involving the antero-inferior quadrant alone and 4 involving the postero-inferior quadrant alone.

Hearing improvement:

The pre-operative mean pure tone average for group A was 34.33±7.3dB; it improved to 24.48±8dB at the end of 3 months and to 22.14±6.5 at the end of 6 months. There was a statistically significant improvement in the hearing post-operatively.

The pre-operative mean pure tone average for group B was 34.25±8dB which improved to 25.25±8.7dB at the end of 3 months and to 22.64±7.4dB at the end of 6 months. There was a statistically significant improvement in the pure tone average post-operatively.

Graft uptake:

Of the 70 patients who underwent type I tympanoplasty in this study, 65 patients had the graft in-situ at the end of six months. Two patients in group A had perforations at the end of six months and two patients in group B had a medialised graft and one had a perforation.

Group A had an overall graft up-take rate of 94.3% whereas group B had a graft up-take rate of 91.4%.

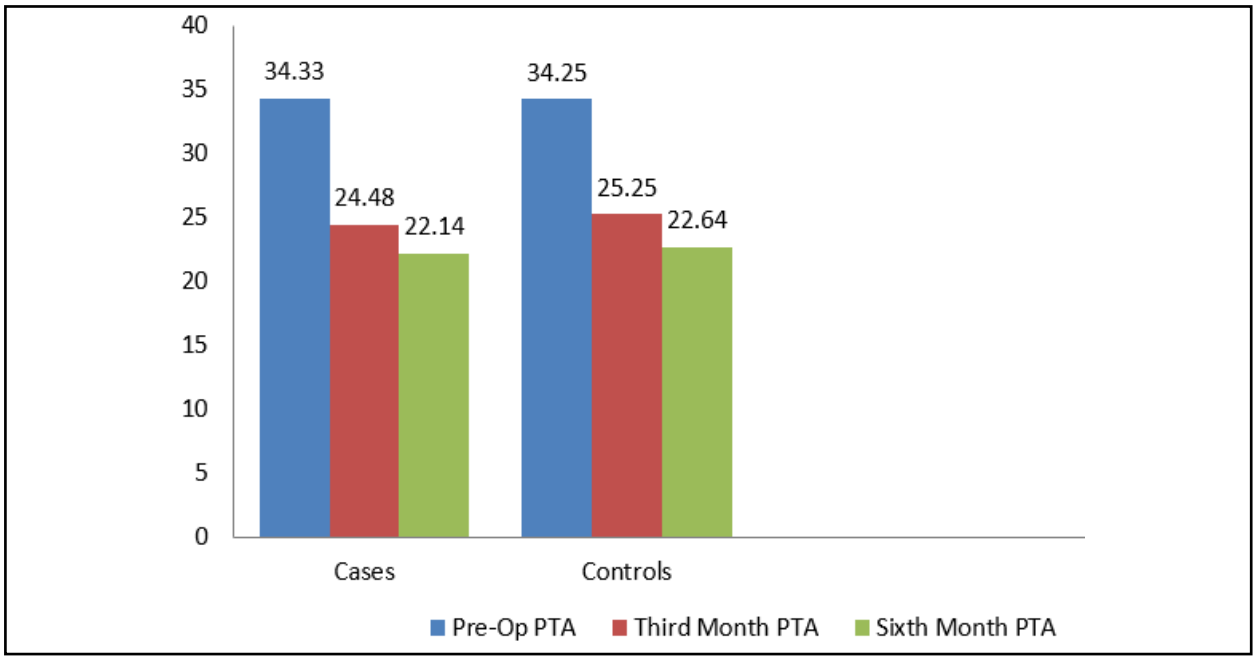

Fig. 1. Comparison of postoperative PTA

Discussion

The aim of our study was to assess and statistically analyse the hearing improvement and graft up-take in type I tympanoplasty done with fibrin glue as compared to conventional techniques. A total of 70 patients were divided randomly into two groups (A and B) of 35 each using RAS software.

The standard procedure used in this study was type I tympanoplasty done via a post-aural approach with a temporalis fascia graft by underlay technique. The placement of the fibrin glue was done after the placement of the graft and repositioning the tympano-meatal flap, along the edges of the perforation. Similar method of placement of graft and application of fibrin glue was done by Yuasa et al and Sakagami et al.[3,4] But Lai and Propst in their study placed the graft lateral to the tympanic membrane and used fibrin glue to secure the graft.[5]

None of our patients developed allergic reaction to the fibrin glue.We observed that there was a statistically significant improvement (p value=0.0000) in the pure tone average post-operatively when recorded at the third month and a further improvement though minimal was noted in the pure tone average at the sixth month in both the groups. In some cases the pure tone average worsened at the sixth month when compared to the third month; this could be associated with the subjective nature of the pure tone audiometry test as there were no obvious signs noted on examining the ears of these patients.

A mean hearing improvement of 12.19 dB was noted in group A while in group B, a hearing improvement of 11.61 dB was noted. Similar hearing improvement was reported by Yuasa et al.[3] Maeta et al published their results comparing simple myringoplasty done with and without fibrin glue and inferred that the simple method with fibrin glue had the advantage of good hearing prognosis over orthodox myringoplasty.[6] But in our study though the improvement in hearing with fibrin glue was better it was not statistically significant.

We recorded a graft up-take rate of 94.3% in group A and 91.4% in group B. Similar graft up-take rates were observed by Yuasa et al and Lai & Propst in their studies.[3,5] Maeta et al had a graft up-take rate of 90.8% in 109 patients who underwent orthodox myringoplasty and 79.8% in 84 patients who underwent simple myringoplasty with fibrin glue.[6] Though in our study

the conventional group had a comparable graft up-take rate to Maeta's study, the graft up-take rate in the fibrin glue group is significantly less compared to our study as well as the other studies mentioned above. Masayuki et al. have recorded a graft uptake of 91% in patients undergoing myringoplasty with fibrin glue.[7] However that study had a sample size of 11 patients only.

In our study there were 11 subtotal perforations in both the groups. In group A all 11 had successful graft up-take (100%) at the end of six months. Whereas in group B 2 out of the 11 cases presented with a medialised graft leading to a graft up-take rate of 81.8%. Thus, fibrin glue has a particular advantage in large perforations. Fitzgerald et al observed that fibrin glue helped in fixing of fascia grafts in subtotal perforations during tympanoplasty.[8] Maeta et al observed that though the overall graft up-take was poor compared to orthodox myringoplasty, the use of fibrin glue in large perforations produced better hearing outcomes and better graft up-take rates.

Though the use of fibrin glue has no effect on hearing improvement in the postoperative period, it helps in securing the graft following tympanoplasty.

Conclusion

The use of fibrin glue in type I tympanoplasty is not an extensively studied subject. The graft up-take rates were better in group A (94.3%) compared to group B (91.4%) at the end of six months, though the difference was not statistically significant. None of the patients in our study had an adverse allergic reaction to the fibrin glue. Hence the use of fibrin in middle ear surgeries is safe and can be used without fear of adverse reactions. The cost of fibrin glue prevents its incorporation into the standard procedure of type I tympanoplasty but it provides an advantage in securing the graft in patients with large perforations and hence should be considered in patients with subtotal perforations.

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A Study of Aetiological Profile of Unilateral Sensorineural Hearing Loss

Prasenjit Gangopadhyay,[1] Bipin Kishore Prasad,[2]

ABSTRACT

Introduction

It is necessary to identify the aetiology of sudden sensorineural hearing loss for proper management. Despite advancement in the field of diagnostic radiology, immunochemistry and genetic studies, there are still many cases of USNHL where a definite cause cannot be identified. In this study, an attempt has been made to identify the aetiological factors responsible for unilateral sensorineural hearing loss (USNHL).

Materials and Methods

Seventyfive patients with acquired unilateral sensorineural hearing loss without chronic otitis media were included in the study. Hearing was assessed by tuning fork test and pure tone audiometry. Special tests were done to differentiate between cochlear and retrocochlear pathology, to objectively assess hearing loss and to diagnose nonorganic hearing loss. Radio-imaging was done to diagnose skull bone fractures, space occupying lesions in internal auditory meatus and cerebellopontine angle or intracranial pathologies. Biochemical analysis of blood, immunoglobulin and serological assay were done to rule out specific causes.

Results

Majority of patients were within 21-30 years of age. 37 patients presented with sudden and remaining with progressive hearing loss. Majority (57.3%) were found to have idiopathic cochlear pathology. Amongst the remaining, there were 8 cases of acoustic trauma, 4 each of Meniere's disease and cerebellopontine angle tumour and 3 each of Noise-induced hearing loss, labyrinthitis and Non-organic hearing loss. There were 2 cases of meningitis and 1 each of barotrauma, connective tissue disorder, iatrogenic trauma, fracture of petrous bone and cerebrovascular accident.

Conclusion

Most of the studies have been done on sudden sensorineural hearing loss. Current study, including sudden and progressive cases, is hence an attempt to ascertain aetiological profile of unilateral SNHL.

Keywords

Hearing Loss, Sensorineural; Unilateral; Idiopathic; Aetiology

Unilateral sensorineural hearing loss (USNHL) is one of the most intriguing situation faced by Otolaryngologists among the patients attending out-patient clinics. The condition is not only very difficult to treat for the doctors but can be embarrassing and frustrating for patients also. For proper management of this condition, it is necessary to identify the underlying cause.

In recent years there has been a huge advancement in the field of diagnostic radiology, immunochemistry and genetic studies. A sea change has come in the audiological battery of tests with the introduction of newer sophisticated audiological tests. Because of this, definite aetiological factors are now found in a good number of cases having USNHL. However, despite all possible investigations, there are still many cases of USNHL where a definite cause cannot be identified.

In this study, an attempt has been made to identify the aetiological factors responsible for USNHL, guide the treatment protocol for individual cases and to ascertain the prognosis in each case. Cases of USNHL based on history and clinical finding have been studied and data

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has been analysed statistically using standard statistical methods.

The aim of this study was to establish the diagnosis of USNHL, determine its aetiology and locate the site of pathology. The cases were then managed accordingly.

Material and Methods

This prospective observational study was carried out in the ENT department of a tertiary care centre over a period of 2 years. Seventy five consecutive patients with USNHL who attended our out-patient department (OPD) or were admitted in various wards of the hospital were included in the study, were included in the study and the data was analyzed using standard statistical methods.Cases of chronic otitis media (COM) with mixed hearing loss, congenital SNHL, hereditary causes and those who were unwilling to participate in the study were excluded from it.

A detailed history was taken, general physical examination and thorough ENT evaluation was done. Hearing assessment was done using tuning fork test, free field hearing (FFH) and pure tone audiometry (PTA) in all cases. Special audiological tests like short increment sensitivity index (SISI), alternate loudness balance test (ABLB), tone decay test were done to differentiate between cochlear and retro cochlear pathology. Brainstem evoked response audiometry (BERA) was done to objectively assess the hearing loss and to diagnose nonorganic hearing loss. Electrocochleography (ECoG) was done to estimate the ratio between summation potential and action potential (SP:AP) to diagnose Meniere's disease. Caloric test was done to see the involvement of peripheral vestibular system.

Magnetic resonance imaging (MRI) of brain with gadolinium enhancement was done in all cases to assess the internal auditory meatus (IAM), cerebellopontine (CP) angle and other pathologies like meningitis, vascular anomaly and cerebrovascular accident (CVA). High resolution computed tomography (HRCT) of temporal bone was done in selected cases of head injury with suspected temporal bone fracture.

Haematological tests including complete haemogram and biochemical parameters were done to rule out co-morbidities in all cases. Double Sandwich ELISA test for detection of IgM antibodies of TORCH (Toxoplasma, Rubella, Cytomegalovirus, Herpes Simplex) pathogens was done to rule out infective causes. Other tests like Veneral Disease Research Laboratory test (VDRL), lipid profile, thyroid profile, Widal test for Typhoid, serum Angiotensin-converting enzyme (ACE) for Sarcoidosis, prothrombin time (PT), partial thromboplastin time (PTT) were done to rule out other pathology. Serological tests like Antinuclear antibody (ANA), double stranded DNA (dsDNA), cytoplasmic and perinuclear antineutrophil cytoplasmic antibody (cANCA and pANCA) were done to rule out connective tissue disorders. Human Immunodeficiency Virus (HIV) screening was done in all cases.

Wherever cause of hearing loss could be found, the treatment was directed at the definite diagnosis. In idiopathic cases, treatment was largely empirical constituting oral steroids,vasodilator and vitamins. They were also counselled regarding the nature of their illness and the measures they should take to protect the remaining hearing ability in the affected ear and to protect the normal ear.

Results

There were 52 male (69.3%) and 23 (30.7%) female. The majority of patients (34.7%) in our study were within the age group of 21-30 years, mean age being 38.6 years. Only one patient was under 20 years of age and two patients were more than seventy years of age (Fig. 1).

37 patients (49.3%) presented with sudden sensorineural hearing loss (SSNHL) which is defined as hearing loss of more than 30 dB, in three or more contiguous frequencies, occurring within a period of 72 hours.[1] Remaining 38 patients (50.7%) presented with progressive hearing loss. 15 patients (20%) attended for medical advice within one month of onset of hearing loss whereas 60 patients (80%) presented after a month.

In our study 57 patients (76%) had associated tinnitus which started along with hearing loss. No patient complained of pulsatile tinnitus. In 22% of the patients,

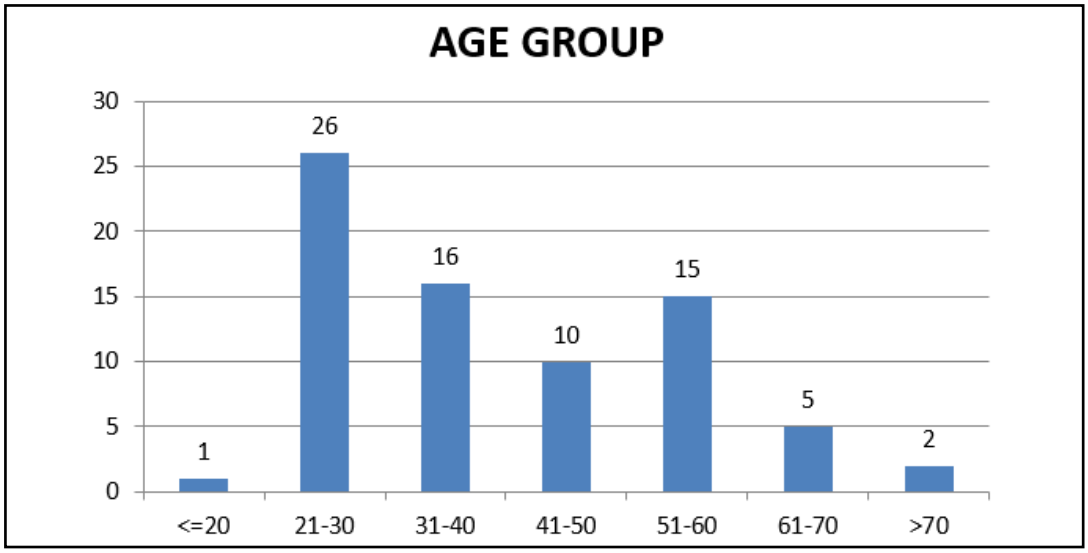

Fig. 1. Age distribution of patients

tinnitus interfered with their daily activities and sleep whereas in 78% of cases it was not troublesome. Giddiness was an associated symptom in 31 patients (41.3%). Among them, 4 patients had severe rotatory vertigo lasting for more than one hour but less than one day along with aural fullness and fluctuating hearing loss suggestive of Meniere's disease. Three patients had severe vertigo with nausea and vomiting which lasted for more than one day associated with sudden onset hearing loss suggestive of labyrinthitis. Remaining patients had nonspecific giddiness associated with hearing loss. 27 patients (36%) complained of aural fullness in ipsilateral ear during the onset of hearing loss. Three patients (4%) had the history of chronic exposure to loud noise whereas 8 patients (10.7%) had history of exposure to high intensity noise just before the onset of hearing loss. Out of 4 patients (5.3%) having preceding history of head injury, only one had fracture of temporal bone involving bony cochlea.

In tuning fork tests, the findings were consistent in 72

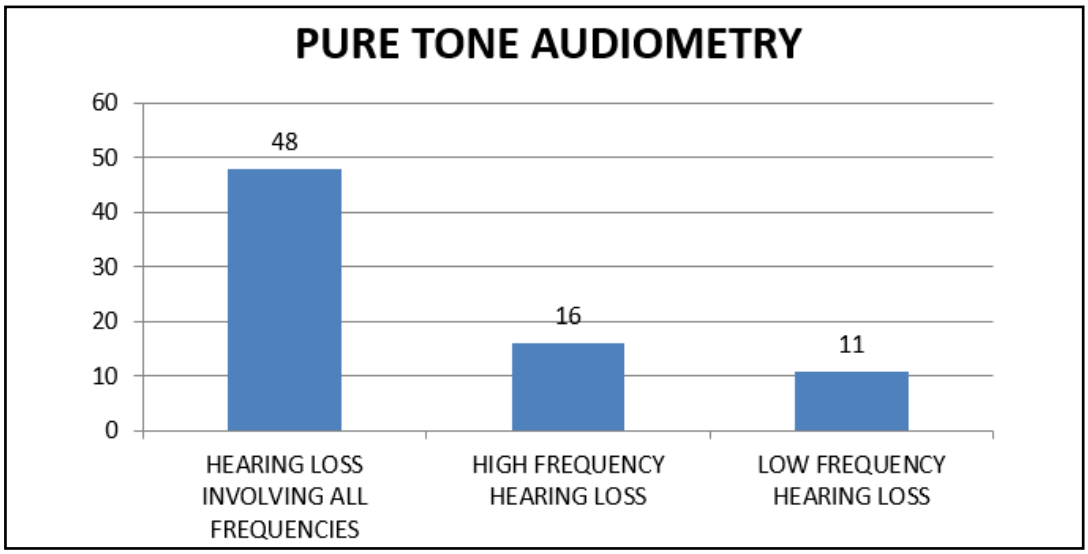

Fig. 2. Frequency related hearing loss in pure tone audiometry

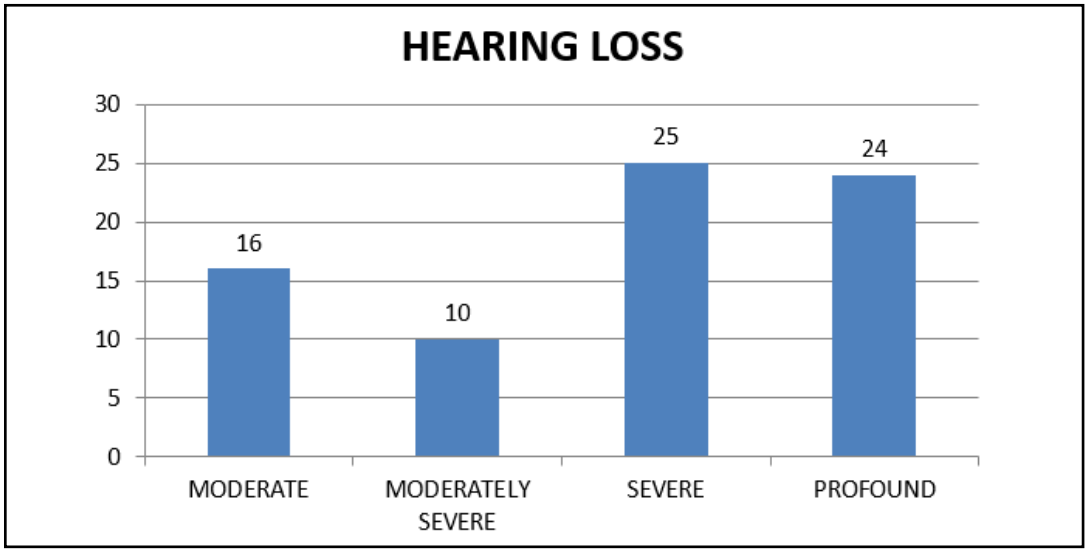

Fig. 3. Distribution of severity of hearing loss

patients (96%) with their history and clinical findings. Remaining 3 patients were later diagnosed as cases of non organic hearing loss (NOHL). PTA was done in all cases. 48 patients (64%) had hearing loss involving all frequencies, 16 patients (21.3%) had high frequency hearing loss whereas 11 patients (14.7%) had low frequency hearing loss (Fig. 2).

16 patients (21.3%) had moderate hearing loss, 10 patients (13.3%) had moderately severe hearing loss, 25 patients (33.3%) had severe hearing loss and 24 patients (32%) had profound hearing loss (Fig. 3).

Bi-thermal caloric test was done in all cases. If found absent, it was repeated with ice cold water to see any response before labelling the case as dead labyrinth. Caloric response was absent on the side of hearing loss in 20 patients (26.7%), reduced compare to healthy side in 28 patients (37.3%) and absolutely normal in 27patients (37%) (Fig. 4).

Otoneurologic examination was normal in 67 patients (89.3%) whereas some abnormality was detected in 8

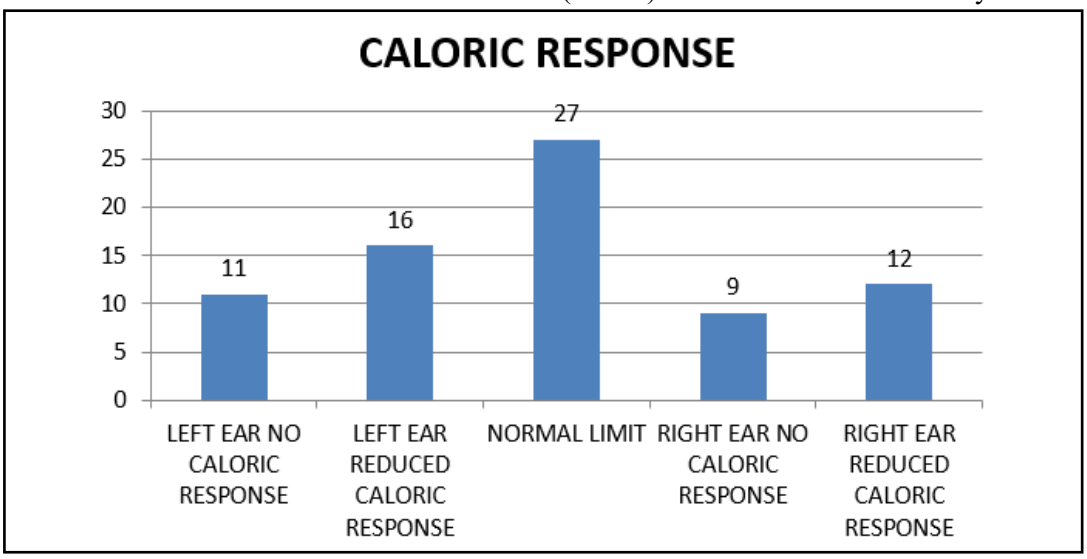

Fig. 4. Distribution of caloric response

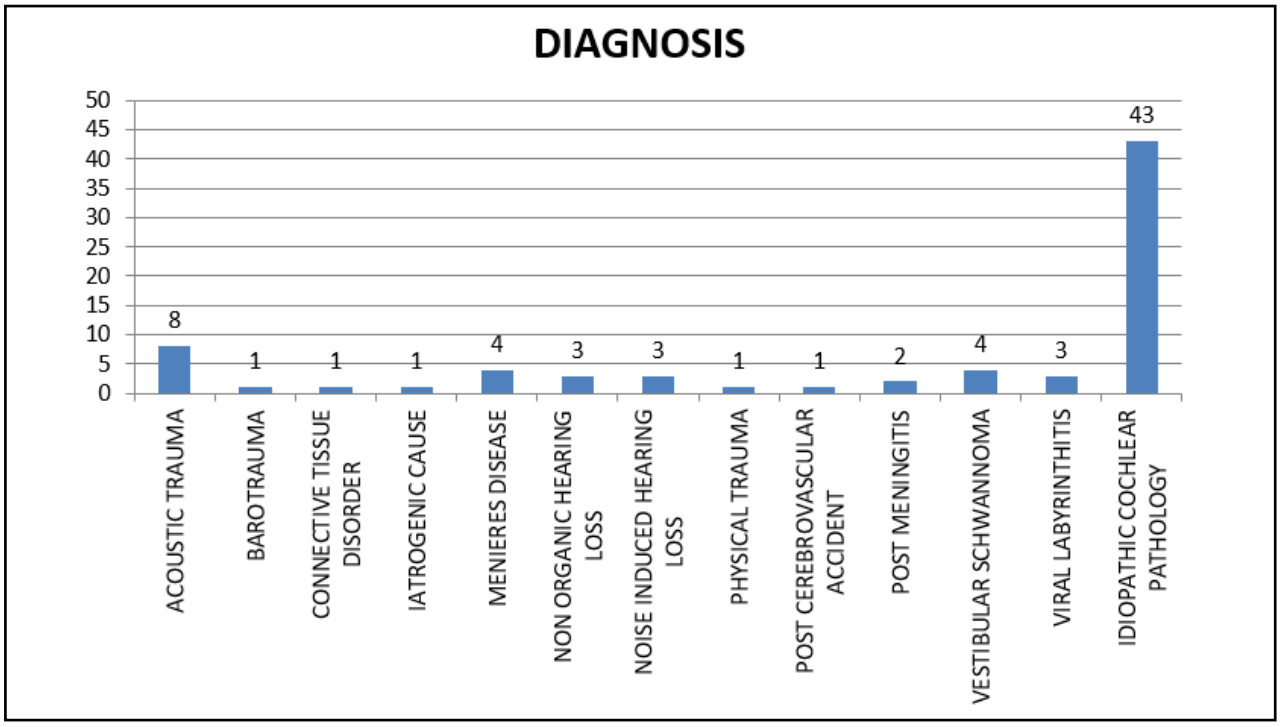

Fig. 5. Aetiological pattern of USNHL

cases (10.7%). Among those cases, cerebellar tests were abnormal in 5 cases, 2 patients had nystagmus towards the side of pathology and one patient had nystagmus opposite to the side of hearing loss.66 patients (88%) had cochlear pathology (SISI score >90 and tone decay <5dB) and 6 patients (8%) had retro cochlear pathology (SISI score <20% and tone decay >30dB). ECoG showed increased SP:AP ratio only in 4 patients (5.3%). Findings in BERA were consistent with hearing loss in 72 patients (96%), whereas 3 patients were found to be malingerers.

HRCT of temporal bone was done in 4 cases with history of head injury and showed fracture line across cochlea in only one case. Gadolinium enhanced MRI of brain, CP angle and IAM was abnormal in 8 cases (10.7%). 4 of them were found to have vestibular schwannoma at CP angle, two had communicating hydrocephalus following meningitis, one had cerebellar infarction and one patient had multiple cerebral infarcts.

Complete hemogram was found to be deranged in 8 patients (10.7%); 2 patients with SSNHL onset in high altitude area showed features of polycythaemia, two patients had reduced platelet count, three had leucocytosis and one patient had increased INR. Blood glucose estimation in 14 patients (18.7%) showed hyperglycaemia. Deranged lipid profile was found in 24 (32%) cases. In 13 cases both cholesterol and triglycerides were elevated, in 4 cases only cholesterol level was elevated and in 7 cases serum triglycerides were increased. 9.3% of cases had associated Hypothyroidism.

Anti DsDNA antibody was found in 4 (5.3%) cases. Among them, only one patient had full blown features of connective tissue disorder along with unilateral sensorineural hearing loss. pANCA and cANCA were positive in 3 of cases (4%). In our study, majority (57.3%) were found to have idiopathic cochlear pathology (Fig. 5).

4 patients (5.3%) had complete recovery of hearing – hearing threshold being 20dB, 23 patients (30.7%) had partial recovery of hearing – hearing gain more than 11dB but thresholdremaining higher than 20dB and remaining 48 patients (64%) had shown no recovery of hearing - hearing gain between 0 to 10dB only.

Discussion

Just as we use two eyes to see in three dimensions, we use two ears to perceive the world of sound around us. This "dimensional hearing" is made possible by binaural hearing.

A person with monaural hearing loses the ability to 'map' the sound in space, pick out soft sounds and to separate a single voice from the surrounding background noise. USNHL is relatively uncommon as compared to bilateral SNHL. Audiometric data of 252 patients suffering from hearing loss in an Indian retrospective study showed that 163 patients (66.5%) had SNHL,out of which only 6 cases (3.7%) had USNHL.[2]

Age distribution:

Unilateral hearing loss, though not common in paediatric age group, is found in both children and adults. In children, it is mostly detected on screening. They do not, as a routine, present as OPD cases. In our study age of patients ranged from 15-73 years, mean age being 38.6 years; where 34.7% were within the age group of 21-30 years. Bansal et al in their study found that age of patients ranged from 9 years to 76 years (mean age being 41.5 years), maximum patients were in 3rd decade (23.87%), followed by 2nd (21.29%) and 4th decade (21.29%).[3]

Sex distribution:

In our study, 52 cases (69.3%) were male and 23 cases (30.7%) were female. Our finding showed a slight variance with Bansal et al, who in their study group of 155 pure USNHL cases, found that 88 patients (56.77%) were males and 67 (43.23%) were females. This is in sync with WHO Global Estimate on Prevalence of Hearing Loss, 2012, which states out of 328 million adult with disabling hearing loss, 183 million are male and 145 million are female.[4]

Laterality:

Sharma et al, among pure unilateral cases, reported right ear involvement in 48.2% of cases and left ear involvement in51.8% of cases,[5] which is similar to the findings in our study where right ear was affected in 45.3% of cases and left ear in 54.7% of cases.

Onset:

SSNHL was found in 37 (49.3%) patients while the rest (50.7%) presented with gradual onset of hearing loss. In the study done by Bansal et al,only 12 cases (7.74%) had sudden onset of USNHL while 143 (92.26%) had gradual onset.[3]

Duration of hearing loss:

In our study, 15 (20%) patients sought ENT consultation within a month of onset of hearing loss whereas 60 (80%) patients presented later. It is one of the known prognostic factorsbecause initiation of definitive treatment after ten days of onset of hearing loss has been related to poorer recovery of hearing compared to those who had been treated promptly.[6]

Associated tinnitus:

In our study 76% of cases had associated tinnitus which started along with hearing loss. Tinnitus has been reported to be only an accompanying symptom in a study by Edizer et al,[7] without influencing the prognosis. On the other hand, tinnitus has been reported as a prognostic factor correlated with better recovery rates in other studies.[8,9]

Associated giddiness:

41.3% cases in our study had vertigo as an associated symptom along with hearing loss.Presence of vertigo, which has been reported to occur in as much as 40% of patients with sudden hearing loss, has been shown to be a negative prognostic factor.[9]

Audiological tests:

Table 3 shows that hearing loss in our patients was from moderate (21.3%) to profound (32%). There was no case of mild hearing loss suggesting that mild unilateral hearing loss was not noticed by the patients or was ignored by them. This finding was in direct contrast with the findings of Bansal et al where 34.2% of USNHL

cases were of mild degree.[3] Tone decay test and SISI, done to differentiate between cochlear and retro cochlear pathology, were suggestive of cochlear pathology in 66 patients (88%) and retro cochlear pathology in 6 patients (8%). BERA, done to objectively measure the hearing loss, was corroborative with findings in PTA in 72 patients (96%). 3 patients were found to be malingerers. ECoG showed increased SP:AP ratio only in 4 patients

Imaging studies:

MRI brain, in our study, showed abnormal findings in 8 cases (10.7%) with 4 patients (5.3%) diagnosed to have vestibular schwannoma. Findings are similar to the study conducted by Robert et al (2000) where high resolution fast spin echo MRI revealed abnormality in 11.8% cases in a series of 1070 patients of USNHL. Among them, 5.2% cases were vestibular schwannomas and the rest were other pathologies including vascular causes.[10]

Relevant blood tests:

14 patients (18.7%) had hyperglycaemia in our study. Pre-existing microvascular lesions in diabetic patients has poor prognosis in SSNHL and raised post prandial blood glucose level could be a risk factor indicator for cochlear dysfunction in them.[11] Lipid profiles were deranged in 24 patients (32%) in our study. In a study conducted by Cadoni G et al (2005) regarding the diagnosis, treatment and outcome of SSNHL, deranged lipid profile was not found to have any bearing in hearing recovery.[12] Hypothyroidism was found in 7 patients (9.3%) in our study. In a study conducted by Narozny W et al (2006) regarding the prognostic factors in SSNHL, hypothyroidism was associated with poorer hearing recovery compared to those who were euthyroid6. Anti DsDNA antibody was found in 4 patients (5.3%) whereas pANCA and cANCA were positive in 3 patients (4%).

Among them, only one patient had full blown features of connective tissue disorder along with USNHL without any other co-morbidities. Serum ACE estimation, screening for HIV, TORCH antibody, VDRL test were negative in all cases. None of the blood tests led to the aetiology of hearing loss except one case of connective tissue disorder. Although there was one case of polycythemia with the onset of hearing loss occurring in high altitude location, hypercoaguability state could not be ascertained. It is, therefore, debatable whether blood tests, due to their low diagnostic yield, are essential in the work up of SNHL or not.

Aetiological profile:

On completion of our study of 75 cases of unilateral hearing loss, though cochlearpathology was identified in 43 patients (57.3%), no specific cause was found to be directly related to the pathogenesis of hearing loss. They have been classified as that of idiopathic cochlear pathology. 8 patients (10.7%) were diagnosed as hearing loss due to acoustic trauma. There were 4 cases each (5.3%) of Meniere's disease and Vestibular schwannoma, 3 cases each (4%) of noise induced unilateral hearing loss, viral labyrinthitis and Non-organic hearing loss. Two patients (2.7%) had communicating hydrocephalous following meningitis. One case (1.3%) each could be attributed to barotrauma, connective tissue disorder, iatrogenic sensorineural hearing loss following surgery for chronic otitis media, head injury with fracture of petrous apex involving bony cochlea and cerebrovascular accident with infarction in ipsilateral posterior inferior cerebellar artery.

The comparative study of aetiologies of unilateral SNHL, as found in our study, in studies done by Sharma et al,[5] Usami et al[13] and the meta-analysis done by Chau JK[14] et al throws interesting facts (Table I). Where most of the studies find Idiopathic SNHL as commonest cause, Sharma et al reported only 7.09% cases to be idiopathic. Presbycusis, which did not even feature as a cause in USNHL in most of the studies, was reported to constitute 78.72% in the study by Sharma et al, which also reported 1.41% cases of otosclerosis and 2.13% cases of ototoxicity leading to USNHL.

Acoustic trauma, which was the second most common aetiology in our study, did not e feature in other studies. Usami et al reported 15.7% cases of USNHL due to otological diseases out of which 12.5% were due to chronic otitis media. Other studies reported only 4.7% to 8% cases due to otological causes, that to none due to COM. The 3rd most common aetiology was quite

Table I: Comparative study of aetiological pattern in USNHL

AETIOLOGY		OUR STUDY (N=75)	SHARMA ET AL (N=141)	USAMI ET AL (N=172)	CHAU JK ET AL
Idiopathic		43(57.3%)	10 (7.09%)	94 (54.6%)	71%
Infectious diseases	Viral: Mumps, Measles, Herpes	-	-	1 (0.58%)	12.80%
	Bacterial Labyrinthitis	3 (4%)	-	-	
	Meningitis	2 (2.7)	-	-	
Otologic disease	COM	-	-	22 (12.8)	4.70%
	Meniere's disease	4 (5.3%)	5 (3.54%)	-	
	Ear surgery	1 (1.3%)		4 (2.3%)	
	Otosclerosis	-	2 (1.42%)	-	
	Ototoxicity	-	3 (2.13%)	-	
	Autoimmune	1 (1.3%)	2(1.42%)	1(0.58%)	
Trauma	Temporal bone fracture	1 (1.3%)	6 (4.25%)	3 (1.7%)	4.20%
	Barotrauma	1 (1.3%)	-		
Vascular/ Haematologic		1	-	-	2.80%
Neoplastic		4 (5.3%)	1 (0.7%)	9 (5.2%)	2.30%
Other causes	Acoustic trauma	8(10.7%)	-	-	2.20%
	Noise induced HL	3 (4%)	1(0.7%)	-	
	Non-organic HL	3 (4%)	-	10 (5.8%)	
	Presbyacusis	-	111	-	

Table II: Statistical analysis of causative factors in USNHL

AETIOLOGY	% OF CASES IN THE PRESENT STUDY	% OF CASES IN STUDY BY JUSTIN K CHAU ET AL (2010)	P VALUE	SIGNIFICANCE
Infectious disease	2.7	12.8	0.008	Significant
Trauma	3.9	4.2	0.947	Not significant
Vascular cause	1.3	2.8	0.488	Not significant
Neoplastic causes	5.3	2.3	0.311	Not significant
Other causes	5.3	2.2	0.293	Not significant
Idiopathic	57.3	71	0.061	Not significant

intriguing. It was CP angle tumour in our study, where as in the study by Usami et al it was NOHL in the study by Usami et al and Temporal bone fracture in the study by Sharma et al and in Meta-analysis by Chau JK et al. The study by Fetterman et al identified a definitive cause in only 10% of cases which is in contrast with our finding of 42.7%.[15]

'Test for equality of Population Proportion' was used for analyzing data. An α level of 5% has been taken and hence any p value <0.05 has been taken as significant. SPSS software version 16 has been used for the analysis. Statistical analysis done after comparing our result of causative factors in USNHL with the result of study conducted by Chau JK et al (2010)[14] for sudden USNHL showed statistically significant difference only in infectious disease as an aetiology. There was no statistical significant difference in idiopathic, traumatic, vascular, neoplastic or other etiological factors (Table II).

Conclusion

Unilateral SNHL can be of sudden or progressive. Scientific data is lacking in etiological study of USNHL where both sudden as well as progressive hearing loss cases have been evaluated. Most of the studies have been done on sudden SHHL and some have been done on paediatric unilateral SNHL. Authors could find only one study by Bansal et al[3] which, though included unilateral SNHL in the age group of 9 years to 72 years, did not elaborate on etiological factors. Our study, which included both sudden and progressive cases, is hence a unique attempt to ascertain aetiological profile of unilateral sensorineural hearing loss.

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Demographic Profile of Hearing Deficiency in a Peripheral Referral Hospital - A Five Year Study

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ABSTRACT

Introduction

This present study is an attempt to study the demographic characteristics of individuals presenting with hearing loss in a peripheral tertiary care hospital using the available database of pure tone audiometry results.

Materials and Methods

A retrospective, observational, descriptive study was conducted over a period of 5 years in the Department of ENT of a peripheral tertiary care hospital wherein all subjects having a pure tone audiometry were included in the study. The records of PTA done were analyzed followed by systematic analysis.

Results

A total of 9790 individuals inclusive of 5566 males and 4224 females were studied. Maximum number of individuals belonged to the age group of 21-30 years. Nearly 63% of total subjects suffered from Bilateral hearing loss. Sensorineural hearing loss was most prevalent type of loss. Mild degree of loss was most prevalent. Adolescents and young adults comprised the bulk of the study population. Sensorineural hearing is the most common type. Bilateral hearing loss is more frequent. Mild degree of loss is most frequent.

Conclusion

This study emphasized the 'Composite parameter distribution' in addition to the classical single parameter demographic profile of deafness in a remote tertiary care hospital. Adolescents and young adults comprised the bulk of the study population. Sensorineural hearing is the most common type. Bilateral hearing loss is more frequent. Mild degree of loss is most frequent.

Keywords

Audiometry, Pure Tone; Hearing Loss; Demography

The ear is a marvellously complex and sensitive organ. Unfortunately, damage to the organ, whether through disease, physical insult, long term exposure to excessive noise, some drugs or simply the effects of aging, can cause the ear to malfunction. The result of malfunction is usually to produce some degree of deafness.[1]

Diseases of the ear have profound effect on the health and quality of life of millions of people around the globe. A significant proportion of cases of hearing loss are due to common ear diseases i.e. Ear wax, External auditory canal infections, Otomycosis, ASOM, CSOM, OME etc, which if diagnosed early and managed properly can significantly reduce the burden of decreased hearing.[1](Table I)

According to Census 2011 data of India; nearly 1 in every 5 differently capable individuals suffers from hearing loss.

The ability to communicate is a crucial aspect of human life as auditory sense is very important for communication of any kind. Hearing impairment is a major morbidity which is often undiagnosed and more often unreported in peripheral healthcare centres of our country. For proper feedback and planning regarding future management, a proper database is mandatory which is often lacking in our system. Thus this present study is an attempt to study the demographic characteristics of individuals presenting with hearing loss in a peripheral tertiary care hospital

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Table I: Disease load of hearing loss estimated by WHO (2012)[2]

7328 million (91%) of these are adults (183 million males, 145 million females) and 32 (9%) million of these are children
The prevalence of disabling hearing loss in children is greatest in South Asia, Asia Pacific and Sub-Saharan Africa.
Approximately one-third of persons over 65 years are affected by disabling hearing loss.
The prevalence of disabling hearing loss in adults over 65 years is highest in South Asia, Asia Pacific and Sub-Saharan Africa.

using the available database of pure tone audiometry results.

Materials and Methods

The study was conducted in the Department of otorhinolaryngology of a peripheral tertiary care hospital over a period of five years (2012-16). The study design was retrospective, observational and descriptive in nature. Patients presenting with chief complaint of hearing loss, after clinical examination, were subjected to Pure tone audiometry. The records of pure tone audiometry done during the study period underwent systematic analysis following predesigned pretested semi-structured protocol.[3] The study excluded children below 5 years of age, individuals with severe mental or physical disabilities and the individuals clinically established to be malingering. The data was analyzed to study the demographic characteristics of individuals based on different parameters e.g. age, sex, type, extent and severity of hearing loss among the study population. (Refer to Proforma in Annexure 1 and 2)

Results

A total of 9790 individuals inclusive of 5566 males (56.85%) and 4224 females (43.14%) had a pure tone audiogram done during the study period in our institute and were included in the study after screening. Maximum number of individuals belonged to the age group of 21-30 years (n=1946; 19.87%) followed by 11-20 years (n=1838; 18.77%). (Table II). Altogether a total of 579 individuals were excluded during screening as per exclusion criteria mentioned above.

The distribution of study population based on age showed similar results between both sexes with 1130 males (20.30%) falling in 21-30 years age group followed by 1002 males (18%) belonging to 11-20 years age group. In females 836 individuals (19.79%) belonged to 11-20 years age group followed by 816

Table II: Table showing distribution of study population based on age

AGE GROUPS	TOTAL	PERCENTAGE
06-Oct	813	8.3
Nov-20	1838	18.77
21-30	1946	19.87
31-40	1506	15.38
41-50	1559	15.92
51-60	1140	11.64
61-70	703	7.18
71-80	236	2.41
>=81	49	0.5
GRAND TOTAL	9790	100 (approx)

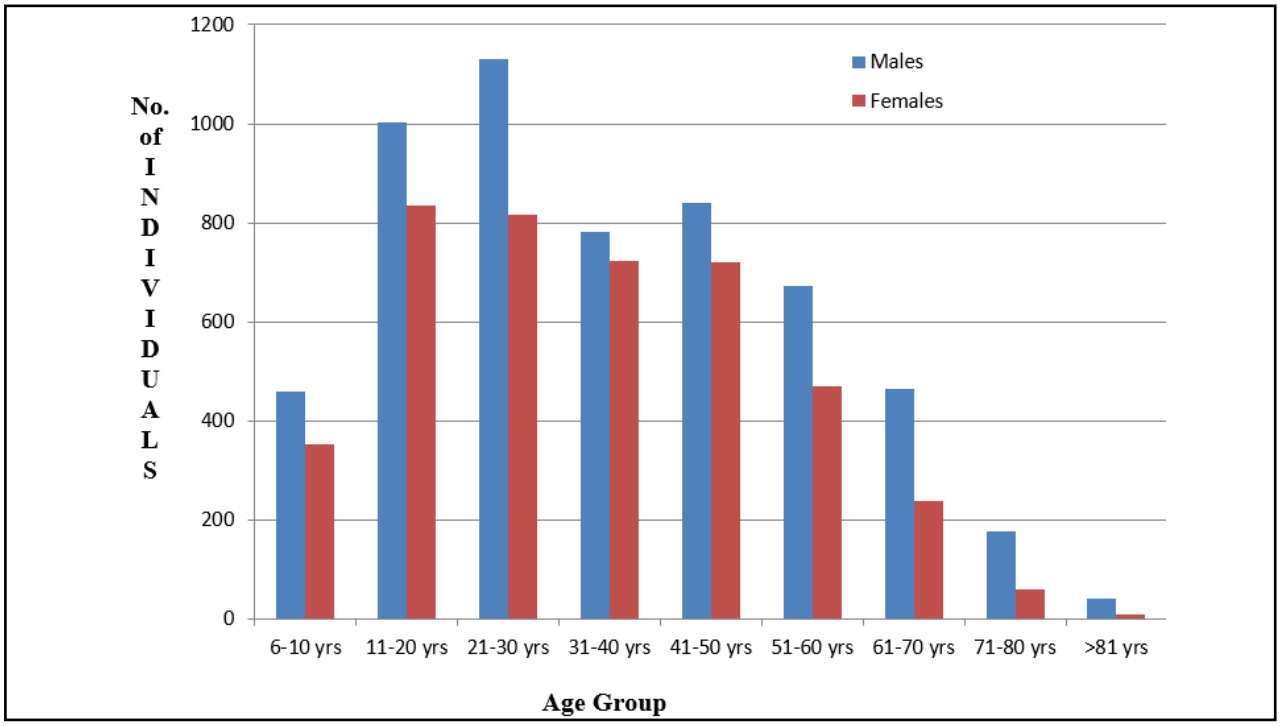

Fig. 1. Clustered bar diagram showing distribution of gender according to age groups

individuals (19.31%) in 21-30 years age group. (Fig-1)

Among 9790 individuals, 6157 (62.89%) suffered from bilateral hearing loss [3494 males (62.77%) and 2663 females (63.04%)].

As far the 'Nature of deafness and the laterality is concerned, 4522 individuals (46.19%) had sensori-neural hearing deficit in right ear and 4468 individuals (45.64%) in left ear. Conductive deafness was present in 1543 individuals (15.76%) in right ear and 1735 individuals (17.72%) in left ear. Mixed deafness was present in 778 individuals (7.94%) in right ear and 811 individuals (8.28%) in left ear. (NOTE: Remainder of the persons had normal hearing for that ear)

As far as the 'Gender distribution of the deafness' is concerned, 48.79% Males had SNHL in right ear and 48.02% in left ear and conductive hearing loss was present in 12.57% individuals in right ear and 14.39% subjects in left ear. Mixed deafness was seen in 6.91% cases in right ear in 7.74% cases of left ear. Amongst females; 42.75% individuals had SNHL in right ear and 42.49% in left ear. Conductive hearing loss was present in 19.96% individuals in right ear and 22.11% subjects in left ear. Mixed deafness was seen in 8.36% cases in right ear in 8.99% cases of left ear.

The 'Age distribution of Deafness' was as follows- Conductive deafness was greatest amongst individuals of 11-20 years (4.00% in right ear and 4.42% in left ear). Sensori-neural loss was highest in 41-50 years age group in right ear (7.68%) and in left ear (7.55%) was seen 51-60 years age group. Mixed loss has been found to be greatest in 41-50 years age group (1.77% in right ear and 1.93% in left ear).

The 'Degree of hearing loss' , as per classification forwarded by Waleed et al,[4], it was noted as- of the 9790 individuals tested, 2605 (26.6%) individuals had mild hearing loss in right ear and 2716 (27.74%) in left ear. Moderate loss was seen in 1705 (17.41%) in right ear and 1682 (17.18%) in left ear. Moderately severe hearing deficit manifested in 1039 cases (10.61%) of right ear and 1071 cases (10.93%) of left ear. Severe degree of loss was seen in 968 (9.88%) of right ear and 971 (9.91%) of left ear. Profound deafness was found in 527 (5.38%) of right ear and 549 (5.60%) cases of left ear. Remainder of the individuals had normal hearing.

Table III: Degree of hearing loss in relation to gender

GENDER & SIDE	MILD HL (25-40 DB)	MODERATE HL (41-55 DB)	MODERATELY SEVERE HL (56-70 DB)	SEVERE HL (71-90 DB)	PROFOUND HL (>90 DB)
Males (Right)	25.29%	16.33%	10.68%	10.27%	5.76%
Males (Left)	27.25%	15.97%	10.90%	10.47%	5.64%
Females (Right)	28.33%	18.84%	10.51%	9.37%	4.87%
Females (Left)	28.38%	18.77%	10.98%	9.18%	5.56%

Degree of hearing loss showed similar results across both sexes. (Table III)

Discussion

The disease burden estimations based on sound epidemiological research provide the foundation for appropriate public policy focus and measures for effective management of disease conditions. A significant proportion of cases of hearing impairment (HI) are due to common ear diseases, which if diagnosed early and managed properly can significantly reduce the burden of decreased hearing.

In the present study maximum number of individuals belonged to the age group of 21-30 years followed by 11-20 years and 31-40 yrs. Guleria et al[1] conducted a community based cross sectional study in an urban area where it was found that 29.4% of individuals belonged to the age group of 31-45 years. This correlates well with the age distribution in the present study and also to the fact that the results of this present hospital based study, an institute which caters to both adjacent rural and urban population, can be extrapolated to the general population.[1] With increasing life expectancy along with changes in diet and lifestyle; exposure to chronic noise, ototoxic chemicals and drugs is on the rise with consequent rise in old age deafness with up to 40% individuals above 75 years suffering from disabling hearing loss.[5] Deafness due to old age has been found to be up to eight times more common in USA.[6]

Among 9790 individuals in the present study, 6157 (62.89%) suffered from bilateral hearing loss which comprised of 3494 males (62.77%) and 2663 females (63.04%). In the study conducted by Guleria et al, 60% of the male population was found to be suffering from hearing loss.[1] Prevalence of hearing loss in males was found to be greater in the study conducted by Kalpana et al.[7] Even in USA, the prevalence of hearing impairment predominantly affected males.[6] As far as laterality of hearing impairment is concerned, the study conducted by Guleria et al shows no difference between right and left sides but bilateral impairment was more frequently encountered than unilateral hearing loss.[1] In the study conducted by Asghari et al, the prevalence of hearing impairment had no significant association with gender.[8]

Sensori-neural hearing loss was predominant in the present study and also in the study conducted by Guleria et al,[1] whereas conductive pathology dominated in the study by Kalpana et al.[7] This difference can be attributed to the fact that the study by Kalpana et al involved only school going children rather than general population. Mixed deafness affected least number of individuals in all the articles reviewed. In the present study conductive deafness was greatest amongst individuals of 11-20 years; sensori-neural loss was highest in 41-50 years age group. Mixed loss has been found to be greatest in 41-50 years age group.

In the present study (26.8%) individuals had mild hearing loss in right ear and (27.74%) in left ear. Moderate loss was seen in (17.6%) in right ear and

(17.37%) in left ear. Moderately severe hearing deficit manifested in (10.6%) of right ear and (10.93%) of left ear. Severe degree of loss was seen in (9.82%) of right ear and (9.82%) of left ear. Profound deafness was found in (5.31%) of right ear and (5.60%) cases of left ear. (Note: The results are the average of both sexes). These findings are in unison with the study conducted by Guleria et al wherein mild to moderate degree of hearing loss predominated across the study population.[1] Similar findings were noted amongst the Korean population in the study conducted by Hong et al.[9] The study conducted by Goman et al in USA shows highest prevalence of mild degree of hearing impairment which is in concordance with our study.[10] Even the study conducted by Asghari et al on Iranian population revealed most number of individuals with grade 1 hearing impairment with an increase in grade of hearing loss with increasing age.[8]

Conclusion

The demographic profile of the deafness population is sine qua non for any comprehensive planning to address the problem. However, profile of individual parameter e.g. age, gender, type of deafness etc. often does not reflect the actual burden of the problem. In that case, distribution of composite parameters e.g. 'Age related type of deafness' or 'Age related degree of deafness' become more helpful. In the present study, effort has been made to emphasise this aspect of 'Composite parameter distribution' in addition to the classical single parameter demographic profile of deafness in a remote tertiary care hospital.

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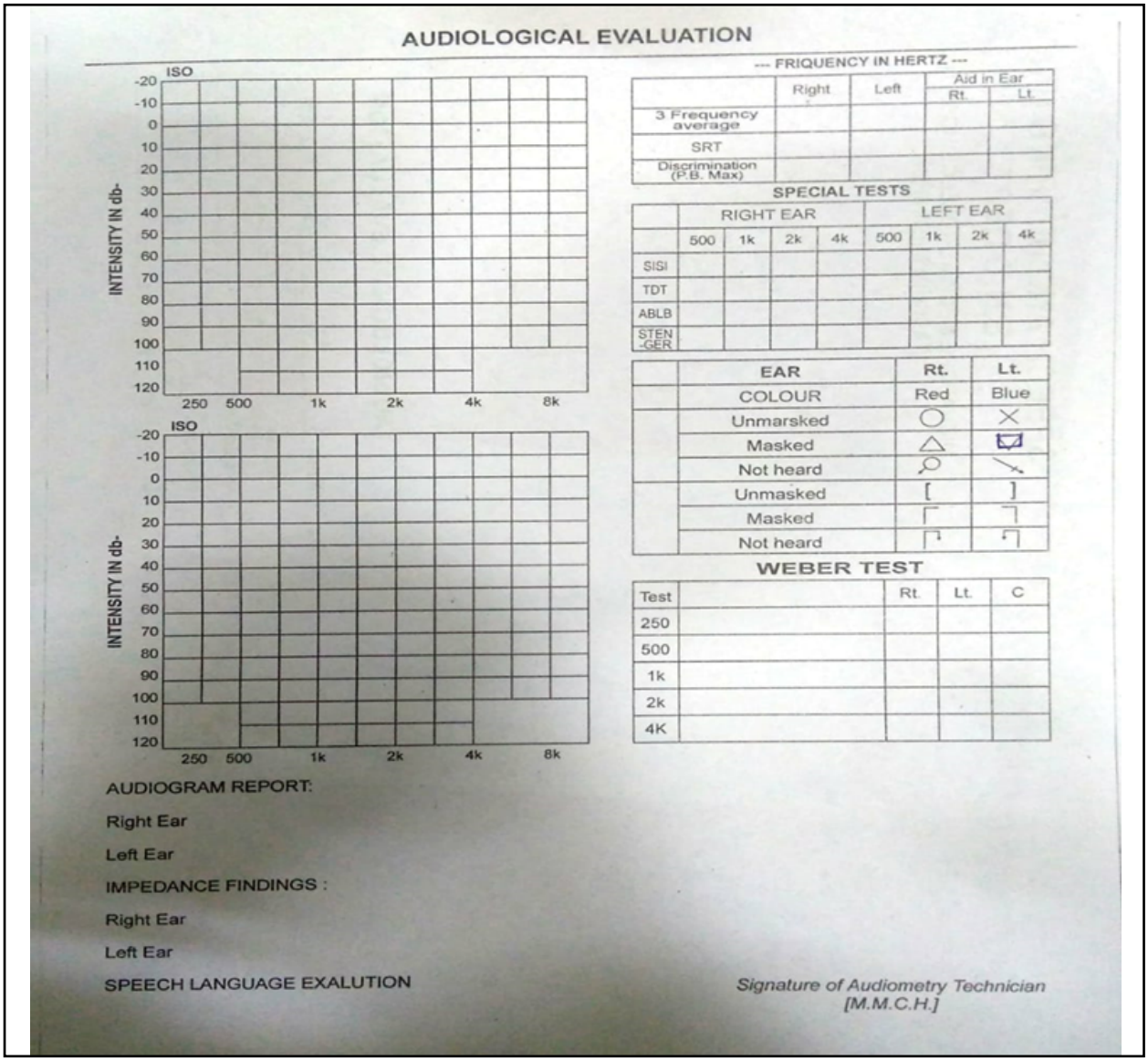
ANNEXURE 1

Proforma of Recording the Audiological Evaluation used in our study

1. Name:
2. Age:
3. Sex:
4. Type of Hearing Loss
   a. Right ear: Conductive/Sensori-neural/mixed
   b. Left ear:Conductive/Sensori-neural/mixed
5. Degree of Hearing Loss
   a. Right ear: Mild/Moderate/Moderately severe/ Severe/Profound
   b. Left ear: Mild/Moderate/Moderately severe/ Severe/Profound
6. Unilateral/Bilateral Hearing Loss



ANNEXURE 2

(Proforma used in Reference Number 3)

SOUTH AUSTRALIAN HEARING STUDY Location : _____ File No:_____

Name:_____ Date of Birth: _____

Main Lifetime Occupation: _____ Sex: M/F

This audiogram shows:

Left Right

[ ] [ ] Normal hearing across all frequencies
[ ] [ ] Sensorineural hearing loss
[ ] [ ] Conductive hearing loss
[ ] [ ] Mixed hearing loss

Overall degree

[L] Mild/Moderate/Severe/Profound
[R] Mild/Moderate/Severe/Profound

Unilateral/Bilateral

Left Right

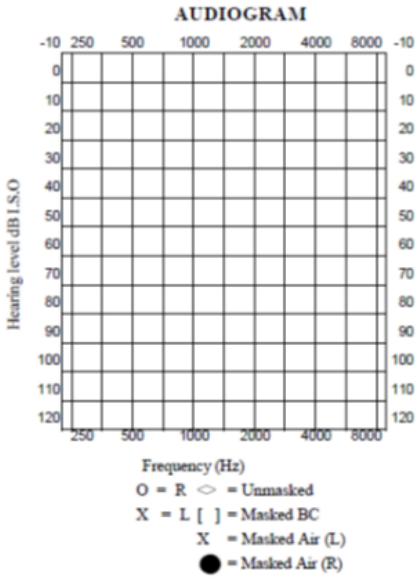
[ ] [ ] Better ear
[ ] [ ] Worse ear
[ ] Symmetrical

Date:____/____/____

Tester:_____

Recommendations

- Monitor hearing levels regularly
- Wear hearing protection
- Seek further audiological services
- Consider hearing aid fitting
- Contact G.P. for ENT investigation
- Consider hearing support services eg Better hearing Aust
- Other _____



Hearing Threshhold Levels

Ear	250	500	1000	2000	3000	4000	6000	8000
Left air								
bone	---				---		---	---
Right air								
bone	---				---		---	---

dB

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Audiologists are University Graduates who have extensive specialist training at Post-graduate level.

Audiologists specialise in the assessment, prevention and non-medical management of hearing impairment and associated disorders of communication

Clinical Study to Determine Occult Vestibular Dysfunction in Patients of Chronic Otitis Media using Computerized Static Posturography

D K Singh,[1] Salil Kumar Gupta, [1] Vijay Bhalla, [1] Sheetal Raina, [1] Abha Kumari [1]

ABSTRACT

Introduction:

Various studies have shown high incidence of subjective vestibular dysfunction in cases of chronic otitis media (COM). Evaluation of vestibular dysfunction in chronic otitis media patients is becoming an integral part of comprehensive management of COM. In our study, we have evaluated vestibular dysfunction in patients with COM, using computerized static posturography, an objective technique in contrast to other subjective tests of vestibular dysfunction.

Materials and Methods

In this prospective case control study done over a period of 1.5 years, 50 cases of COM and 50 healthy controls were included and they underwent Computerized Static Posturography. Parameters taken were Somaesthetic, visual and vestibular scores in both antero-posterior (AP) and medio-lateral (ML) axis; and in combined axis (Antero-posterior +Medio-lateral) and these scores were compared with those of healthy controls.

Results

Total 50 cases of COM (average disease period - 5.7 years), of both sexes, with age range of 15-60 years and mean age of 31.58 years were taken. On analyzing above mentioned parameters using SPSS software, we found no significant difference in vestibular function in cases of COM as compared with healthy individuals.

Discussion

The outcome of computerized static posturography can be quantified with respect to changes in center-of-force sway amplitude, distance, or velocity, which, by virtue of not being burdened by subjective interpretation, its results can be, documented both graphically and numerically.

Conclusion

This study, further solidified with objective evidence, raises a question on COM without complications being directly responsible for vestibular dysfunction.

Keywords:

Otitis Media; Vestibular Dysfunction; Posturography

The peripheral end organ of the vestibular system is the first sensory system to develop preceding cochlear development and is developed by 49 days of gestation. The vestibular system includes the inner ear (three semicircular canals, the utricle and the saccule) and parts of the brain that process the sensory information involved with controlling balance and eye movements. The cochlea and vestibule are anatomically and functionally related to each other and any dysfunction of one or both of them may result in vestibular disorder and subsequent deficit in balance function.[1]

Infection of the inner ear occurs via spread of the pathogenic organism through one of three pathways - meninges, middle ear space, or bloodstream. The most commonly reported infection occurs in acute or chronic otitis media (COM) due to passage of infection through

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the round or oval windows.[2] Both human and animal studies have indicated that the round window is of more significance in the pathologic process. The loss of hair cells occurs due to toxins and enzymes absorbed from the large intercellular spaces in the round window.[2,3]

Various studies done in the past to assess vestibular dysfunction in chronic otitis media patients with or without dizziness or vertigo have shown high incidence of vestibular dysfunction.[4] Thus diagnosing and evaluating vestibular dysfunction in chronic otitis media patients is essential and should begin with a comprehensive history taking, physical examination and vestibular function tests.[4]

Recently, posturography has become an important part of functional investigation aimed at identifying and assessing vestibular dysfunction. It is an objective technique used to measure postural stability on static or dynamic measuring platforms. Thus it is not burdened by subjective interpretation and the result can be documented both graphically and numerically. Computerized static posturography is carried out by placing the subject in standing pasture on a fixed platform connected to sensitive detectors, which are able to detect the tiny oscillations of the body.[5]

Dynamic posturography involves perturbing the subject's posture by means of a foam cushion or a movable horizontal and tilting platform. As the subject makes small movements, the sensitive detectors transmit this time varying information in real time to a computer.[6-8] In our study, we have evaluated occult vestibular dysfunction in patients with COM, using computerized static posturography.

Materials and Methods

After taking approval from the Institutional Ethics Committee, we carried out a prospective case control study in the Department of ENT of this tertiary care hospital over a period of one and half year from October 2013 to March 2015, on patients according to the inclusion criteria, which is as below:

Inclusion Criteria

1. Patients with unilateral/bilateral COM (either squamous or mucosal) without overt vestibular dysfunction.
2. Patients with age >5 years and <65 years.
3. Patients without intratemporal or intracranial complications of chronic otitis media.

Exclusion Criteria

1. Patients who have already undergone previous ear surgery.
2. Patients with acute vertigo or overt vestibular dysfunction.
3. Patients with disorders affecting the visual and proprioceptive functions.
4. Patients with any central cause of vestibular dysfunction.
5. Patients currently on vestibular sedatives.
6. Patients with history of ototoxic drug intake.

Control group included 50 healthy subjects with no ear disease, and no known peripheral/central vestibular dysfunction, and willingness to undergo the procedure.

50 patients with COM were selected consecutively as and when they presented during the study period based on inclusion and exclusion criteria. Written informed consent was taken from the patients, and healthy volunteers.

A pre-designed proforma was used to record relevant information from the individual patients selected, and healthy volunteers. A detailed history was taken from all the patients, and as well the healthy volunteers. Otoscopy and Otomicroscopy (if needed) was carried out to determine the presence of COM and findings recorded, such as type of COM, site etc. All patients underwent Computerized static posturography with Synapsys® posturography System (SPS, SYNAPSIS, Marseille, France) which had inbuilt software for posturography data analysis.

The Synapsys® posturography platform (SPS), allows assessment of static and dynamic balance in the normal,, pathological or aging subject. In addition, it is also possible, with this technique to identify the system(s) responsible for balance dysfunction. During same investigation it can classify the various sensory afferents (visual, vestibular, somaesthetic) involved in postural control, by order of importance; which is what makes it truly unique. The platform, due to its motorized system, is able to produce controlled and reproducible

Table I: Test conditions during computerized static posturography

TEST CONDITION	PLATFORM	VISION	DURATION
1	Static	Eyes open	20s
2	Static	Eyes closed	20s
3	Unstable surface (foam)	Eyes open	20s
4	Unstable Surface (foam)	Eyes closed	20s

translational movements of the support and study the patients' postural reactions to the provoked disturbances. The software gives pertinent indications to detect postural deficiencies and risk of falls in pathological and/or elderly patients by quantifying objectively their balance performances.

Hardware composition

The complete system includes:

1. A static platform integrating 3 pressure sensors.
2. A data acquisition system.
3. A software application.
4. A base in foam.
5. An unstable platform.
6. A slip-guard (stepladder + base bars)
7. A translator

The subjects were asked to stand barefoot on the platform with his/her feet aligned to previously determined markings, corresponding to foot size and they were told to stand straight and with arms along the sides of the body, without moving during the whole recording period. Two recordings of each condition were recorded. Evaluation parameters were determined during four test conditions as per Table I.

The parameters evaluated were as follows:

1. Somaesthetic, visual and vestibular scores in both antero-posterior (AP) and medio-lateral (ML) axis.

2. Somaesthetic, visual and vestibular scores in combined axis (Antero-posterior +Medio-lateral).

Data was entered in MS Excel and analyzed using SPSS 22.0. The Somaesthetic, Visual and Vestibular scores were represented using mean and standard deviation. Comparison of Somaesthetic, Visual and Vestibular scores in normal and COM patients was done using Student's t test.

Results

Out of fifty COM patients, 30 were males and 20 were females. The age range was from 15-60 years with mean age of 31.58 years. Control group included 50 healthy subjects with no ear disease and no known peripheral/ central vestibular dysfunction, and willingness to undergo the procedure. Out of fifty in this group, 41 were males and 9 were females. The age range was from 20-45 years with mean age of 34.75 years. (Table II)

Tables III, IV, and V compare the mean scores of all three parameters (somaesthetic, visual and vestibular) in antero-posterior (AP), medio-lateral (ML) and combined axis (AP+ML) between normal and COM group.

36 patients suffered from mucosal type of COM and 14 suffered from squamous type of COM. The duration of COM was from 1 to 9 years with an average duration of 5.7 years.

On posturography, the mean of the Somaesthetic AP score in normal group was 93.6 with standard deviation of 12.9 while the mean of the Somaesthetic AP score in COM group was 94.0 with standard deviation of 12.7. There was no significant difference in the AP scores of normal and COM groups in Somaesthetic parameter as

Table II: Demographic data of subjects

VARIABLE	COM PATIENTS	HEALTHY VOLUNTEERS
Sample Size	50	50
Male : Female	3:2	41:9
Age Range	15-60 yrs	20-45 yrs
Mean Age	31.58 yrs	34.75 yrs

Table III: Comparison of Somaesthetic, Visual and Vestibular AP SCORES in normal and COM patients

PARAMETERS	NORMAL (N=50)		COM (N=50)		P VALUE
	MEAN	SD	MEAN	SD	
Somesthetic	93.6	12.9	94	12.7	0.87
Visual	86.6	15.9	88.1	15.3	0.645
Vestibular	79.6	16.6	80.4	17.2	0.823

the p-value was 0.870.

The mean of the Visual AP score in normal group was 86.6 with standard deviation of 15.9 while the mean of the Visual AP score in COM group was 88.1 with standard deviation of 15.3. The AP scores of normal and COM groups in Visual parameter showed no significant difference as the p-value was 0.645.

The mean of the Vestibular AP score in normal group was 79.6 with standard deviation of 16.6 while the mean of the Vestibular AP score in COM group was 80.4 with standard deviation of 17.2. The AP scores of normal and COM groups in Vestibular parameter also showed no significant difference as the p-value was 0.870.

The mean of the Somaesthetic ML score in normal group was 96.1 with standard deviation of 10.8 while the mean of the Somaesthetic ML score in COM group was 93.2 with standard deviation of 14.0. There was no significant difference in the ML scores of normal and COM groups in Somaesthetic parameter as the p-value was 0.239.

The mean of the visual ML score in normal group was 86.7 with standard deviation of 16.2 while the mean of the Visual ML score in COM group was 82.5 with standard deviation of 18.6. The ML scores of normal and COM groups in visual parameter showed no significant difference as the p-value was 0.240.

The mean of the Vestibular ML score in normal group was 84.9 with standard deviation of 15.6 while the mean of the Vestibular ML score in COM group was 83.1 with standard deviation of 18.4. The AP scores of normal and COM groups in Vestibular parameter also showed no significant difference as the p-value was 0.607.

The mean of the Somaesthetic and Combined score in normal group was 94.9 with standard deviation of 11.7

Table IV: Comparison of Somaesthetic, Visual and Vestibular ML SCORES in normal and COM patients

PARAMETERS	NORMAL (N=50)		COM (N=50)		P VALUE
	MEAN	SD	MEAN	SD	
Somesthetic	96.1	10.8	93.2	14	0.239
Visual	86.7	16.2	82.5	18.6	0.24
Vestibular	84.9	15.6	83.1	18.4	0.607

Table V: Comparison of Somaesthetic, Visual and Vestibular COMBINED SCORE in Normal and COM patients

PARAMETERS	NORMAL (N=50)		COM (N=50)		P VALUE
	MEAN	SD	MEAN	SD	
Somaesthetic	94.9	11.7	93.6	12.2	0.597
Visual	86.7	13.7	85.3	14.9	0.641
Vestibular	82.3	13.9	81.8	14	0.859

while the mean of the Somaesthetic and Combined score in COM group was 93.6 with standard deviation of 12.2. There was no significant difference in the combined scores of normal and COM groups in Somaesthetic parameter as the p-value was 0.597.

The mean of the Visual and Combined score in normal group was 86.7 with standard deviation of 13.7 while the mean of the Visual and combined score in COM group was 85.3 with standard deviation of 14.9. The Combined scores of normal and COM groups in Visual parameter showed no significant difference as the p-value was 0.641.

The mean of the Vestibular and Combined score in normal group was 82.3 with standard deviation of 13.9 while the mean of the Vestibular and Combined score in COM group was 81.8 with standard deviation of 14.0. The combined scores of normal and COM groups in Vestibular parameter also showed no significant difference as the p-value was 0.859.

Thus, on comparison of all the three parameters in both the positions (AP & ML) as well as the combined score, there was no significant difference in patients with COM as compared to normal persons.

Discussion

This prospective case control study was conducted to detect occult vestibular dysfunction in COM patients using computerized static posturography. Although the objective of this study was to evaluate the vestibular

aspect of the balance, the results of visual and somaesthetic inputs also have been studied to provide a comprehensive balance evaluation.

Various studies done in the past have shown high incidence of vestibular dysfunction in COM.[9-11] A study by Lal Siampara et al, in contrast, showed no significant difference in the responses of the diseased and the normal ears on Hot and Cold caloric tests.[12] They had concluded that majority of the cases of COM have little effect on the vestibular function but long duration of the disease may have an adverse effect.

In our study, no patient with COM was detected to have vestibular dysfunction on the basis of their vestibular scores in anteroposterior and mediolateral axis. Their combined scores also were comparable to healthy controls. Apart from vestibular score, the results of visual and somaesthetic parameters were also evaluated in our study in order to provide a comprehensive balance evaluation. These parameters also did not show statistically significant difference when compared with normal persons.

Thus our study has not demonstrated any significant occult vestibular dysfunction in COM patients as compared to healthy volunteers. Our findings are in line with the study of Lal Siampara et al[12] but at variance compared to other studies.[9-11]

Vestibular functions in most of the studies done in the past were assessed mainly by caloric testing. The caloric test assesses only the horizontal semicircular canal. Thus, caloric abnormalities do not necessarily imply that the labyrinth is totally dysfunctional and should be interpreted in light of other tests.[10] In patients of COM open-loop water caloric test cannot be performed due to fear of infection.[13] Similarly, rotation test (Barany chair), Electronystagmography (ENG) & Videonystagmography (VNG) have their limitations.[6, 14,15]

It is possible that vestibular dysfunction reported in other studies might be due to limitations of the technique of testing rather than actual vestibular deficit. On the other hand, posturography recently has been accepted as an important part of battery of functional investigations aimed at identifying and assessing vestibular dysfunctions.[6] It is an objective technique used to measure postural stability on static or dynamic measuring platforms. Thus it is not burdened by subjective interpretation and the results can be documented both graphically and numerically.[16]

Static platform posturography involves stance or tandem stance on a fixed platform with eyes open or closed. This procedure uses the Romberg tests, and the outcome is quantified with respect to changes in center-of-force sway amplitude, distance, or velocity.[5]

Dynamic platform posturography also utilizes Romberg's tests with a fixed platform, but includes test conditions in which the platform and visual environment are moved to reduce the subject's ability to use visual and somatosensory information for balance. All these parameters can also be studied by dynamic posturography. In addition, Dynamic platform posturography incorporates sudden displacements of the platform to test the subject's response to balance perturbations.[7,8]

The reason for not detecting vestibular dysfunction in any COM patient could be due to poor sensitivity of static posturography in identifying occult vestibular dysfunction. Richard P Di Fabio in his study on sensitivity and specificity of platform posturography for detecting vestibular disorders concluded that dynamic and static platform posturography as well as tests of vestibulo-ocular-reflex (VOR) function lack adequate sensitivity to detect vestibular impairment when applied in isolation.[16] It is possible that addiction of dynamic posturography to our static posturography could have revealed occult vestibular dysfunction in our patients.[17,18] Most of the studies which found vestibular dysfunction in COM patients, have used both static and dynamic posturography to detect peripheral vestibular dysfunction.[19]

Conclusion

Hence based on the results of this study we observe that there is no significant difference in vestibular function in cases of COM as compared with healthy individuals when assessed using static posturography. As the sample size of this study is small and has used only static posturography, it is important that a larger

study be conducted using both static and dynamic posturography to evaluate the presence of occult vestibular dysfunction in COM patients. However, keeping in mind the limitations of static posturography, the findings may differ if dynamic posturography is added to static posturography.

As mentioned above, duration of COM has also been implicated in presence of occult vestibular function. Most of the studies have found vestibular dysfunction in long standing COM cases only, usually more than 10 years.[4,19] The duration of COM in our patients ranged 1 to 9 years with average of 5.7 years. Hence, it is possible that these patients genuinely did not have vestibular dysfunction and static posturography has detected the same correctly.

Limitations of study –

1. As per demographic analysis of this study (Table II), although the number of cases in COM group and healthy control group is same, the age and sex variable among two groups are not matched, this decreases the strength of study.

2. The COM group have taken in cluster of patients suffering from both COM Mucosal and Squamous. There is abundance of literature proving that COM Squamous is more likely to cause complications than COM Mucosal. Although, cases in this study have been clinically examined for any intratemporal or intracranial complications (as per inclusion criteria), but the possibility of a patient suffering from COM Squamous developing occult vestibular complications cannot be negated. However, Labyrinthine fistula, one of the most common complication leading to occult vestibular dysfunction can be caused by both COM Squamous and Mucosal, incidence being 4-13% among all cases.[20, 21]

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Medial versus Medio-lateral Tympanoplasty in Large Central and Subtotal Perforation – A Prospective Study

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ABSTRACT

Introduction

Large central and subtotal tympanic membrane (TM) perforations are difficult to repair because of less vascularity of anterior TM than posterior TM and the anterior bony overhang that blocks visualization. Some studies reported very encouraging results with the medio-lateral tympanoplasty in such cases. We have undertaken this study to find out efficacy of this technique in large central and subtotal perforations and to compare the results of medio-lateral with medial tympanoplasty.

Materials and Methods

The present prospective study was conducted in the Department of Otorhinolaryngology of a medical college and hospital, West Bengal from January 2013 to December 2014. Patients were alternatively divided into two groups. Medial technique was used in Group I and medio-lateral technique was used in Group II.

Results

Each group comprised of 40 patients each. Maximum number of patients in each group was in the age group of 15-25 years. The overall graft uptake rate in this study was 95% in medio-lateral technique compared to 80% of underlay technique.

Conclusion

The medio-lateral tympanoplasty is suitable for reconstruction of large central or subtotal TM perforation. It takes advantage of both medial and lateral grafting methods while avoiding their pitfalls.

Keywords:

Tympanic Membrane Perforation; Tympanoplasty

One of the common sequelae of chronic otitis media is tympanic membrane (TM) perforation. Large central and subtotal tympanic membrane (TM) perforations continue to be one of the greatest problems in tympanoplasty surgery. Repair of these perforations is less likely to be successful as compared to repair of small and posterior perforations.[1,2] Large central and subtotal TM perforations are difficult to repair because of less vascularity of anterior TM than posterior TM and the anterior bony overhang that blocks visualization.[3]

There is a greater risk of re-perforation and obliteration of the anterior part of middle ear cavity.[4] Although the lateral (overlay) technique has a higher success rate for reconstructions of large central and subtotal TM perforations, serious complications may occur. These problems have been managed by a variety of surgical techniques, such as the use of William's microclip,[5] sandwich graft tympanoplasty,[4] over-underlay tympanoplasty.[6] Yet, a still better method is needed to repair anterior and subtotal TM perforations. Jung and Park in 2005 reported very encouraging results with the medio-lateral tympanoplasty, where graft is placed medially to the posterior half of TM perforation and

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laterally to the anterior half of perforation. This method is a hybrid of the medial and lateral tympanoplasty techniques thus takes advantages of both methods.[7] In light of very encouraging results of medio-lateral tympanoplasty, we have undertaken a prospective study to find out efficacy of this technique in large central and subtotal perforations and to compare the results of medio-lateral with medial tympanoplasty.

Materials and Methods

The present study was conducted in the Department of Otorhinolaryngology of a medical college and hospital, West Bengal. Eighty six patients of either sex in the age group of 15-50 years suffering from chronic otitis media with large central or subtotal perforation were selected for the study from the outpatient department during the period from January 2013 to December 2014. We selected patients with ear free from active discharge for at least 4 weeks; Air bone gap more than 25 dB on pure tone audiogram; good cochlear reserve; without any complication; and no focus of infection in nose and throat. Patients with actively discharging ear; hearing loss >60 dB; marked deviated nasal septum or active sinus disease; history of ear surgery in the past were excluded from the study. Written informed consent was taken from all patients and their guardian. This study was approved by Institutional Ethical Committee. Six patients did not turn in follow up. So they were excluded from the study. These patients were alternatively divided into two groups. Each group comprised of 40 patients. Medial technique was used in Group I and medio-lateral technique was used in Group II.

History of all the patients was documented in detail. All of them were subjected to thorough clinical examination and the otoscopic findings were confirmed by examination of the ear under microscope (EUM). Pure tone audiogram of both ears for air and bone conduction were done. Patients were posted for tympanoplasty operation under local anaesthesia and sedation after doing all routine investigations. Autologous temporalis fascia graft was used in all cases. Also trans-canal technique was used in all the cases.

In medial tympanoplasty technique graft was advanced under the posterior tympanomeatal flap and under the malleus handle to the anterior most extent of the perforation and the edges of the graft was tucked under the margin of drum remnant. Small pieces of the gelfoam were used to overlap the junction of rim and graft circumferentially.

In medio-lateral tympanoplasty technique vertical canal incisions were made at the 12 and 6 O'clock position. The 6 o'clock incision was extended right up to the annulus. The 12 o'clock incision was made down to a few millimetres above the annulus to preserve blood supply because the anterior canal skin was used as the superiorly based flap. Connecting incision was given 3 mm away from the annulus on posterior canal skin. Posterior tympanomeatal flap was elevated. With a curved round knife, horizontal incision was made in the anterior canal skin. The distance of the anterior horizontal canal incision from the anterior annulus should be about the same as the diameter of the perforation. After the incision the anterior canal skin was elevated medially. The antero-medial canal skin flap was elevated up to the annulus or margin of the tympanic membrane perforation. At the annulus, only the squamous epithelial layer of the tympanic membrane was carefully elevated to the anterior half of the perforation edge, leaving the anterior annulus intact. The temporalis fascia was grafted medially for the posterior half of the perforation and the handle of the malleus and was grafted laterally over the annulus in the anterior half of the perforation. Antero-medial skin was rotated to cover perforation and fascia in a superiorly based flap. Antero-lateral canal skin was replaced. Gelfoam soaked in antibiotic solution was placed lateral to the tympanic membrane. An umbilical tape coated with framycetin ointment was placed in external auditory canal.

Patients were discharged next day with antibiotic, analgesic and antihistaminic. Each case was reviewed at 1 week, 3 week, 2 months, 6 months and 1 year. Post-operative pure tone audiometry was done at 6 months and 1 year.

Results

Total 80 patients were divided into two equal groups randomly. Medial tympanoplasty was done in Group I and medio-lateral tympanoplasty was done in Group II.

Table I: Distribution of patients according to size of perforation

SIZE OF PERFORATION	TOTAL NUMBER OF PATIENTS	HEALTHY VOLUNTEERS
	GROUP I	GROUP II
Subtotal Perforation	34 (85%)	36 (90%)
Large Central Perforation	06 (15%)	04 (10%)

Table II: Relationship between graft take-up and size of perforation

SIZE OF PERFORATION	TOTAL NUMBER OF PATIENTS	HEALTHY VOLUNTEERS
	GROUP I	GROUP II
Large	4/6 (66%)	4/4 (100%)
Subtotal	28/34 (82%)	34/36 (94%)
Overall	32/40 (80%)	38/40 (95%)

Maximum number of patients in each group was in the age group of 15-25 years. There were total 44 males and 36 females. All patients in this study had a history of ear discharge in the past, though the ear was apparently dry for at least four weeks before they were taken up for tympanoplasty. In both groups 15% patients had bilateral ear involvement. Size of the perforation was defined as follows[3]: Pin-point; Small (smaller than one quarter of the tympanic membrane size); Medium (up to half the size of tympanic membrane); Large (up to

Table III: Follow up examination in Group I

OTOSCOPIC FINDINGS	10TH DAY	3RD WEEK	2ND MONTH	6TH MONTH
Intact graft	-	32 (80%)	32 (80%)	32 (80%)
Anterior sulcus blunting	-	-	-	-
Graft lateralization	-	-	-	-
Discharge	-	8 (20%)	-	-
Residual perforation	-	8 (20%)	4 (10%)	2 (5%)
Graft rejection	-	-	6 (15%)	6 (15%)

Table IV: Follow up examination in Group II

OTOSCOPIC FINDINGS	10TH DAY	3RD WEEK	2ND MONTH	6TH MONTH
Intact graft	-	36 (90%)	36 (90%)	38 (95%)
Anterior sulcus blunting	-	-	-	-
Graft lateralization	-	-	-	-
Discharge	-	04 (10%)	-	-
Residual perforation	-	-	02 (5%)	-
Graft rejection	-	-	02 (5%)	02 (5%)

three quarters the size of tympanic membrane); Subtotal (when only annulus remains). In Group I, 34 (85%) cases had subtotal perforation whereas six (15%) cases had large central perforation. In Group II, 36 (90%) cases had subtotal perforation, whereas four (10%) cases had large central perforation (Table I). In Group I, four (10%) cases had medially retracted handle of malleus.

In rest 36 (90%) cases handle of malleus was normal. In Group II, two (05%) cases had medially retracted handle of malleus; while it was partially necrosed in two (05%) cases and normal in 36 (90%) cases. In Group I, four (10%) cases had moist the middle ear mucosa. While the middle ear mucosa was normal in 36 (90%) cases. In Group II, two cases had moist middle ear mucosa, rest were normal. Tuning fork test was done in all patients with 512 Hz frequency tuning fork and results were compared with the audiogram. Based on the pure tone audiogram, hearing loss was classified as mild (24-40 dB), moderate (41-55 dB), moderately severe (56-70 dB), severe (71-90 dB) or profound (>90 dB).[19] In both the groups 95% of the patients had conductive hearing loss in the range of 25-40 dB and four patients had a loss of 45 dB. The overall graft take-up rate in group I was 80% and in group II it was 95% (Table II). In Group I, discharge was noted in eight patients which was resolved by changes of antibiotic and six patients

Table V: Average post-operative hearing gain in Group I

HEARING GAIN	NUMBER OF PATIENTS
0-5 dB	08 (20%)
5-10 dB	00 (0%)
10-15 dB	20 (50%)
15-20 dB	10 (25%)
>20 dB	02 (05%)

Table VI: Average post-operative hearing gain in Group II

HEARING GAIN	NUMBER OF PATIENTS
0-5 dB	02 (05%)
5-10 dB	00 (0%)
10-15 dB	14 (35%)
15-20 dB	22 (55%)
>20 dB	02 (5%)

had graft rejection and two had residual perforation (Table III). In Group II, discharge was noted in four patients which was resolved by changes of antibiotic and two patients had graft rejection and two had perforation which was healed with application of chemical cautery (Table IV).

In Group I, the average preoperative A-B gap was 35.5 dB while the average postoperative A-B gap was 21.5 dB, giving an average postoperative gain of 14 dB. Majority of patients 30 (75%) had a gain in the range of 10-20 dB. Two patients had a gain of more than 20 dB (05%), eight (20%) had 0-5 dB gain. This included two patients with perforation and six with graft rejection (Table V). In Group II, the average preoperative A-B gap was 36.5 dB with average postoperative gap of 18.5 dB thereby average gain of 17.5 dB. 36 (90%) patients had a hearing gain of 10-20 dB, while two (5%) had gain of more than 20 dB. Rest two (5%) patients had no gain of hearing. This group comprised of two cases with graft rejection (Table VI).

Discussion

It has been shown that one of the most important factors in the success of tympanoplasty is the size and site of the perforation.[1,2] The success rate of repairing small and posterior perforations can be higher than 90% but the success rate dropped to 67% in the repair of anterior and subtotal perforations.[8]

Using flourescein dye, Applebaum and Deutsch demonstrated that the anterior tympanic membrane is less vascular than the posterior part. Because of this reduced vascularity, there is greater risk that epithelialisation and healing may not occur in the anterior part prior to necrosis and re-absorption of the graft. In this area of the ear drum, there is also a problem with fixation of the fascia graft.[3]

One of the main problems in subtotal perforation is the lack of anchorage and support for the graft, especially with the underlay technique. It has been stated that the graft acts as a scaffold for the migration of squamous epithelium and mucosa. Hence persistence of the graft in correct position is more critical to the successful closure of the large perforation than small one.

Schuknecht (1976) believes that surgical technique is most important factor in the success of tympanoplasty especially for anterior and subtotal perforations.[9] Two classic methods for reconstruction of TM perforation have been medial and lateral technique. Each technique has its advantages and disadvantages.[10,11]

In medial technique, the graft is placed medial to the drum remnant after excision of the edges of the perforation. It is simple and easy to perform particularly when perforation is small. There is no anterior sulcus blunting or lateralization of graft. But there is a chance of reduction in the middle ear space. Moreover medial technique is not suitable for subtotal or total perforations.[12-16]

In lateral technique the epithelium of the drum remnant is elevated from the fibrous layer, this usually being done in continuity with the flaps made from skin after giving the circumferential incision. Advantages of this technique are visualization of anterior meatal skin is usually complete, which is important in cases where the perforation reaches the anterior annulus; the middle ear space is not compromised as the graft is applied outside the existing layer of middle ear mucosa. Although the lateral technique has a higher success rate for the reconstruction of anterior or subtotal TM perforations, serious complications may occur. Disadvantages are squamous cyst formation from remnants of epithelium left behind the skin flaps; blunting of the anterior sulcus due to accumulation and organization of blood deep to skin graft or due to lateral deposition of the fascia graft over the anterior canal wall; lateralization of the graft which is considered to be a continuation of a process of blunting. In the later postoperative period the graft may become lateralized due to contractile tightening of the graft tissue.[12-16] In lateralization, the TM loses contact with the conductive mechanism of the middle ear resulting in hearing loss.

Various techniques have been described to overcome the problems. Stage J and Back-Pederson (1992), presented a study in which the graft was placed lateral to the handle of malleus in underlay tympanoplasty.[17] Kartush et.al. (2002) introduce the term over-underlay tympanoplasty. It was a contribution of two classical techniques; in which the graft is placed lateral to the handle of malleus, and under the drum remnants and

annulus.[18] Farrior (1989) in the management of anterior and subtotal tympanic membrane perforations described the sandwich graft tympanoplasty which uses both an internal and external layer of areolar fascia, plus immediate epithelial coverage and reported a 98% success rate.[4] Weider (1981) reported a 99% success rate with the use of the William's microclip to secure the fascia graft.[5] Cody DT and Taylor WF (1973) reported the use of double fascia grafts, one medial and one lateral to the drum remnant, which yielded a higher rate of successful perforation closure than using single layer grafting techniques.[19] Hung et.al. (2004), used antero-superior anchoring technique and reported success rate between 85.7% to 100%.[20] Gerlinger et.al. (2006) described anterior anchoring technique combining the anterior "pull-back" method and reported 100% graft take up rate.[21]

Jung and Park (2005) described medio-lateral tympanoplasty for anterior or subtotal tympanic membrane perforation and reported 97% success rate.[7] In 2009 Jung et. al. presented a comparative study between medial and medio-lateral graft tympanoplasty and reported a success rate of 97% using the medio-lateral technique.[22] In this technique, the fascia graft is placed medial to the handle of malleus and posterior half of the tympanic membrane perforation but lateral to the anterior half of the perforation. This method is a hybrid of the medial and lateral graft techniques that takes advantages of both methods. The advantages include prevention of anterior fall away of the fascia; stability of the graft; prevention of lateralisation of graft; better blood supply because anterior canal skin is rotated as a rotational flap rather than free graft. Jung & Park[7] (2005) and Jung et.al.[22] (2009) reported no case of lateralization.

In the present study age group ranged from 15-50 years; patients younger than 15 years were excluded from the study. This age group was selected due to its likelihood of their proper and regular follow up as well as to rule out failure of graft acceptance due to repeated upper respiratory tract infections as seen in children, and reduced healing tendency of the elderly. More-over presbycusis tends blur the auditory functions in higher age group.

In the present study maximum number of patients was male (55%) and females comprises of 45% of cases with a male to female ratio of 1.2:1. This is because males in villages are usually in the habit of taking bath in the ponds and are more liable to suffer from COM as compared to females. Also males seek medical advice much more readily than females, as they have more outdoor life and have more interaction with society.

All the ears were free from active discharge at the time of surgery though there was history of ear discharge in the past. However, some authors have reported good results of tympanoplasty in wet ears.[23]

No correlation was observed between the bilateral involvement and the successful outcome of tympanoplasty in the present study. This is in accordance with the study done by Smyth et.al.[24]

The overall graft uptake rate in this study was 95% in medio-lateral technique compared to 80% of medial technique. These results are in accordance to earlier studies by Jung and Park and Jung et.al.[7,22] There was no case of lateralization in the present study like previous studies.

Conclusion

The medio-lateral graft method has been developed and used for reconstruction of large central or subtotal TM perforation. It takes advantage of both the medial and lateral grafting methods while avoiding their pitfalls. A high success rate of 95% similar to other studies provides support in this favour.

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An Open-Label Observational Trial to Evaluate the Possible Effects of Individualized Homoeopathic Medicines in Symptomatic Nasal Polyp

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ABSTRACT

Introduction

Nasal polyps presenting with chronic rhino-sinusitis (CRS) is a commonly encountered condition characterized by nasal obstruction, loss of sense of smell (anosmia), postnasal drip, headache, and sleep disorders. Possibly 60-65% of the populations suffering from CRS has predisposition to nasal polyps. Homoeopathic literature claims to offer successful treatment of nasal polyps; but scarcely subjected to systematic research.

Materials and Methods

A prospective, open, non-randomized, single arm, observational trial of pre-post comparison design was conducted on 44 patients suffering from symptomatic nasal polyps. Sino-nasal outcome test (SNOT-20) and European Quality of Life (EQ-5D-5L) questionnaires were taken as the primary and secondary outcome measures respectively; assessed at baseline and after 3 months. Individualized homoeopathic medicines were prescribed on 'totality of symptoms'. Intention to treat sample was subjected to statistical analysis. Data distribution was examined. Non-parametric Wilcoxon signed rank test and post hoc parametric paired t test were used accordingly. P values less than 0.05 were considered as statistically significant.

Results

Forty four patients were enrolled; 4 dropped out. Skiagrams revealed complete regressions of polyps in 23 (58%) cases. Statistically significant improvements were observed in both the subjective patient-rated outcomes – mean reduction of SNOT-20 scores by 19.9 [sd 15.5; 95% CI 15.5 to 24.2; P < 0.001], EQ-5D-5L questionnaire score by 0.9 [sd 2.6; 95% CI 0.1 to 1.7; P = 0.029]; and EQ-5D-5L VAS by 14.4 [sd 4.7; 95% CI 12.9 to 15.9; P < 0.001].

Conclusion

Homoeopathic medicines showed promising treatment effect in symptomatic nasal polyps. Randomized trials are warranted..

Keywords

Homeopathy; Nasal Polyp; Quality of Life

Nasal polyps (NP) presenting with the symptoms of chronic rhino-sinusitis (CRS) is one commonly prevalent disorders of the nose and para-nasal sinuses. These are non-cancerous growths within the nose or sinuses characterized by trouble breathing through the nose, loss of smell, decreased taste, post-nasal drip, and a runny nose. Possibly 60-65% of the population suffering from CRS have predisposition to nasal polyp.[1]

Incidence of nasal polyp with the symptoms of CRS is seen to be on the rise in correlation to the increasing levels of environmental pollution and stress.[2] CRS is a common disorder, with up to 35 million people being affected annually, and results in over 12 million office visits yearly.[3] The physical symptoms of CRS are

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associated with functional and emotional impairment, which can lead to an overall poor quality of life (QOL).[4,5] Likewise, obstructive sleep apnoea (OSA) is just as common. With up to 40 million Americans affected, it is increasing in prevalence and has been demonstrated in approximately 24% of men and 9% of women. Similar to CRS, it is associated with a poor QOL and functional and emotional impairment.[6,7] CRS is a common health condition in industrial countries concerning 10-15% of the German population.[8]

In the US, it was the most frequently reported chronic disease in a representative cohort of 100,000 adults participating in the National Health Interview Survey 1988.[9] Negative effects of CRS on QOL of the patients have frequently been underestimated. Nevertheless, many patients report higher impacts of CRS on QOL dimensions like bodily pain or social functioning compared with other diseases like angina pectoris, pulmonary emphysema or chronic bronchitis.[10] Economic impact of CRS has rarely been investigated. In 2006, nearly 45,000 patients with CRS were operated in German hospitals.[11] In 1996, the healthcare expenditures for sinusitis in the US were 5.8 billion dollars.[12] Gliklich and Metson[13] performed a break-even analysis and calculated a time period of 7 years until amortization of treatment costs can be achieved by reduced postoperative use of resources. Under these conditions, effective and successful treatment of NPs with CRS has an increasing medical and economic importance. In 1942, the revision surgery rate in 190 patients after trans-facial extra-nasal procedures was nearly 31%.[14] Modern Functional Endo-nasal Sinus Surgeries (FESS) resulted in stable subjective success rates between 70% and 92%.[15,16,17]

Materials and Methods

Trial setting and design: Samples were collected from amongst the patients attending the ENT out-patients. The study protocol was approved by the Institutional Ethical Committee (IEC). The trial protocol (unpublished) and full dissertation was submitted as the postgraduate thesis of the corresponding author to the West Bengal University of Health Sciences.

Inclusion criteria: All diagnosed cases of nasal polyp having symptoms of CRS, age 18 to 65 years, both sexes, patients willing to take part in the study and providing written consent. Patients availing any form of treatment for the same were enrolled after a wash-out phase of 1 month provided they had persistence of relevant signs and symptoms.

Exclusion criteria: Patients opting for surgical intervention, patients receiving active treatment from any other system of medicine, uncontrolled systemic or psychiatric illness, and patients denying consent.

Intervention: All medicines and vehicles in this project were procured from Homeopathy International – a GMP certified firm. All the patients were treated with individualized homoeopathic medicines in 50 millesimal potencies as per need of the case. In 50 millesimal potencies, a single medicated cane sugar globule of poppy seed size (no. 10) was dissolved in 80 ml distilled water with addition of 2 drops of 90% v/v ethanol, 16 doses marked on the vial, each dose of 5 ml was instructed to be taken after 10 uniformly forceful downward strokes to the vial in 45 ml normal water in a clean cup, to stir well, to take 5 ml of this liquid orally, and to discard rest of the liquid from the cup.

Repetition was advised daily or every alternate day depending upon the individual requirements of the case and as decided appropriate by the treating homeopaths. Duration of therapy was 3 months. Single individualized medicine was prescribed on each occasion taking into account presenting symptoms totality, clinical history details, constitutional features, miasmatic expressions, repertorisation using the software RADAR® and consensus between two homoeopaths. Dose was also individualized and was based on the homoeopaths' judgment of susceptibility and consensus. Subsequent prescriptions were generated as per Kent's observations and Hering's law. Participants were assessed similarly by the two homoeopaths in follow-up visits. One of the prescribers possessed a masters degree in homoeopathy with more than 30 years of experience of practicing classical homoeopathy and the corresponding author was a postgraduate trainee at NIH with 3 years of experience. All the homoeopaths involved were affiliated with state councils.

Outcomes: Primary – translated Bengali version of the Sino-Nasal Outcome Test (SNOT) questionnaire; secondary – EQ-5D-5L questionnaire; available and pre-validated Bengali version [User license no. 24882]. The Sino-Nasal Outcome Test 20 (SNOT – 20) was one of the most widely used quality-of-life instruments for sino-nasal conditions[18-21] and was intended for populations of people with rhino-sinusitis, rather than simply rhinitis. The SNOT-20 was a self-administered multiple choice 20 items test that is usually scored with a single summary score (0-5) without domains or subscales. The items were assigned to five subgroups (nasal symptoms, para-nasal symptoms, sleep-related symptoms, social impairment and emotional impairment). The score of the SNOT-20 was calculated by summation of all the symptoms scores. Therefore, scale values of the SNOT-20 ranged from 0 to 100. Additionally, patients could circle those 5 symptoms which have the highest impact on the impairment. This instrument assessed a broad range of health and health- related quality-of-life problem including physical problems, functional limitations and emotional consequence, but unlike many of the quality-of-life instruments designed to measure rhinitis symptoms, this rhino-sinusitis measure was not divided into subscales or domains related to these different areas. Another was the EQ-5D-5L questionnaire.

It was a standardized measure of health status developed by the Euro QoL Group[22] in order to provide a simple, generic measure of health for clinical and economic appraisal. It was applicable to a wide range of health conditions and treatments; it provided a simple descriptive profile and a single index value for health status that could be used in the clinical and economic evaluation of healthcare as well as in population health surveys. EQ-5D was available in 139 languages including Bengali, was designed for self-completion by respondents and was ideally suited for use in postal surveys, in clinics, and in face-to-face interviews. It was cognitively undemanding, taking only a few minutes to complete. Instructions to respondents were included in the questionnaire.[23,24]

Sample size: No relevant data was available on reduction of SNOT score by individualized homoeopathic treatment using an open observational study design over 3 months of intervention. Thus, assuming a medium effect size (d) of 0.5, alpha = 0.05 and power of 90%, to detect a significant difference between two dependent means (mean pre- and post- SNOT scores) by paired t test, we would have required a sample size of 44.

Statistical methods: Intention to treat sample was subjected to statistical analysis. Missing values were replaced by Last value Carried Forward (LVCF) method. Data distribution was examined by histograms, Q-Q plots, Kolmogorov-Smirov and Shapiro-Wilk tests. Descriptive statistics was used to represent baseline data. Inferential statistics was used in terms of non-parametric Wilcoxon signed rank test and parametric post hoc paired t test to compare SNOT-20 and EQ-5D-5L scores those obtained at baseline and after 3 months. P values less than 0.05 were considered as statistically significant. No interim and subgroup analyses were planned. SPSS® IBM® version 20 software for Windows was used for analysis of data. Reporting adhered to the CONSORT[25] and RedHot[26] guidelines for reporting trials, Mathie's criteria for model validity of homoeopathic treatment[27,28] (MVHT), and Saha's criteria for reporting quality of homoeopathic individualization in clinical trials.[29]

Results

Participant flow: As per the pre-specified inclusion and exclusion criteria, 70 patients suffering from nasal polyposis were screened; 26 were excluded on account of various reasons; 44 met the eligibility criteria and were enrolled into the study. Following that, baseline socio-demographic and outcome data were obtained (n=40). After 3 months of intervention, outcome data was recorded again. During course of treatment, 4 dropped out; 40 completed the trial; 44 entered into the analysis. (Fig. 1)

Recruitment: Starting from May 2017 until November 2017, total 44 participants were enrolled in the study.

Baseline data: Twelve socio-demographic features were studied – age (as continuous variable), age groups (categorical variable), gender, residence, duration of suffering, treatment taken, body mass index (BMI; as continuous variable), BMI classes (categorical variable), marital status, education, employment status,

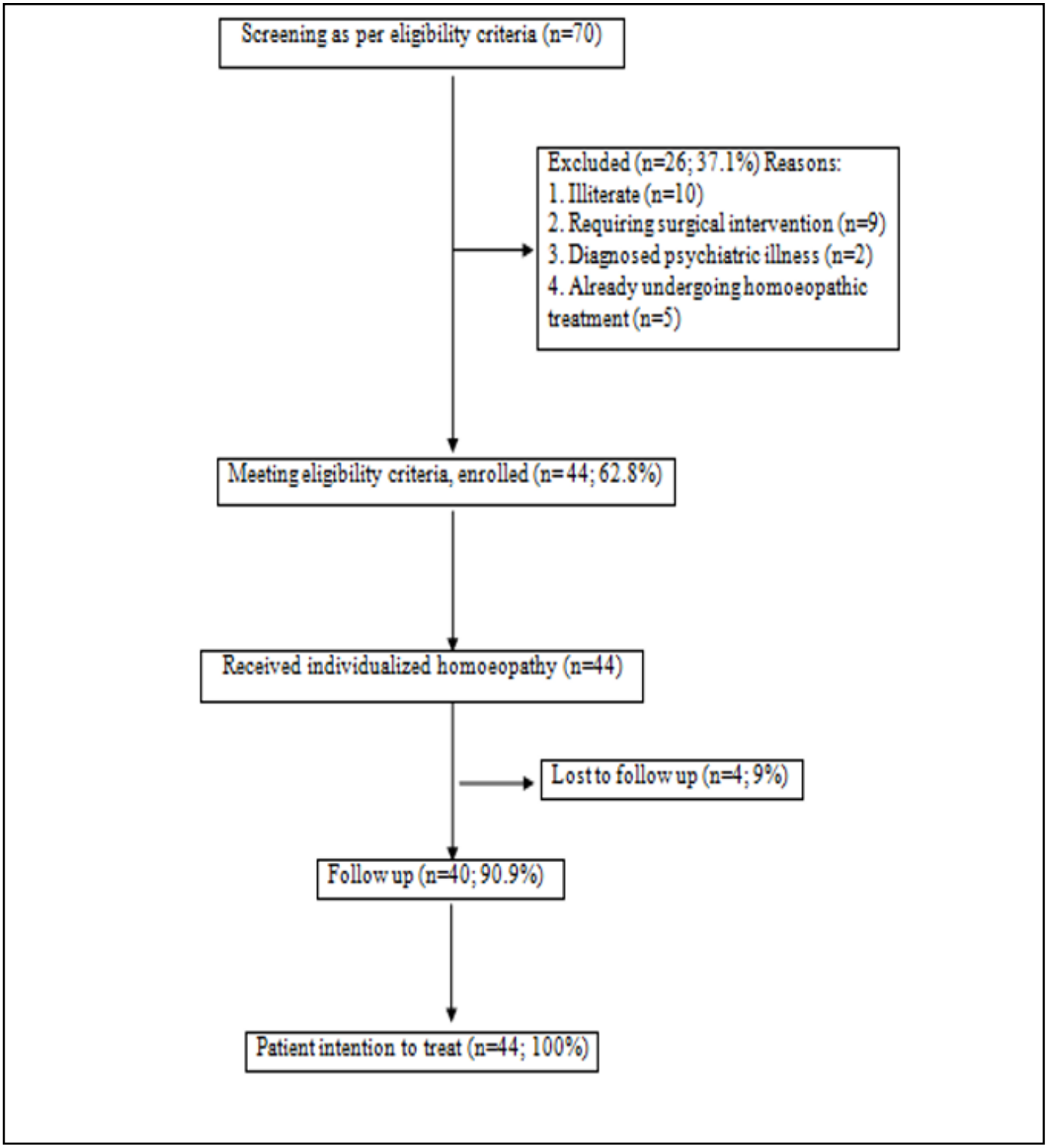

Fig. 1. Study flow diagram

and family income status (Table 1)

Data distribution: It was examined by histograms (Supplementary Data – Figures: 1-6), Q – Q plots (Supplementary Data – Figures: 7-12) and statistical tests – Kolmogorov Smirnov test and Shapiro Wilk test (Supplementary Data – Table 1). Data distribution seemed to follow a mixed pattern – at baseline normal but non-normal after 3 months. Thus, first non-parametric Wilcoxon signed rank test (Table II) was planned to perform; and if significance was detected, then post hoc parametric paired t test (Table III).

Numbers analyzed: All the enrolled patients (N=44) entered into the final analyses.

Changes in outcomes:

1. As per skiagrams of 40 protocol-compliant cases, there were complete regressions of nasal polyps in 23 (58%) cases, partial improvement in 11 (27%) cases and no changes in 6 (15%) cases.

2. After 3 months of treatment, there were statistically significant improvements in SNOT-20 scores, EQ-5D-5L questionnaire scores, and EQ-5D-5L VAS measures (all $P < 0.05$). (Tables II and III, Fig. 2)

Correlation statistics: The correlation scatter plots (Figure: 15 and 16) revealed weak to moderate positive linear relationships between changes in SNOT score and EQ-5D-5L scores.

Medicines used: The following medicines were prescribed – Tuberculinum [n=2; 5%], Thuja occidentalis [n=1; 2.5%], Sulphur [n=2; 5%], Sangunaria canadensis [n=1; 2.5%] Pulsatilla nigricans [n=2; 5%], Psorinum [n=11; 27.5%], Nitric acid [n=2; 5%], Natrum muriaticum [n=1; 2.5%], Hepar sulphuricum [n=3; 7.5%], Dulcamara [n=10; 25%] Calcarea carbonica [n=5; 12.5%], Belladonna [n=1; 2.5%], Arnica montana [n=1; 2.5%]. (Table IV)

Adverse events: No harm, unintended effects, serious adverse events, and homeopathic aggravations were reported during the study period.

Table I: Baseline features

Age Δ (yrs; mean ± sd)	**30.0 ± 10.5**
Age groups (yrs) §	
§ 18 – 25	**20 (45.5)**
§ 26 – 40	**18 (40.9)**
§ Above 40	**6 (13.6)**
Gender §	
§ Male : Female	**30 (68.2) : 14 (31.8)**
Residence §	
§ Rural : Urban	**26 (59.1) : 18 (40.9)**
Duration of suffering Δ (yrs; mean ± sd)	**3.5 ± 2.3**
Treatment taken §	
§ Allopathy	**11 (25)**
§ Homoeopathy	**11 (25)**
§ None	**22 (50)**
BMI Δ (mean ± sd)	**23.5 ± 3.9**
BMI classes §	
§ Underweight to normal	**26 (59.1)**
§ Overweight	**15 (34.1)**
§ Obese	**3 (6.8)**
Marital status §	
§ Single : Married	**19 (43.2) : 25 (56.8)**
Educational status §	
§ 8th std or below	**25 (56.8)**
§ 9th to 12th std	**4 (9.1)**
§ Graduate or above	**15 (34.1)**
Employment status §	
§ Unemployed	**14 (31.8)**
§ Farmer	**5 (11.4)**
§ Business	**19 (43.2)**

Discussion

This prospective, open, non-randomized, single arm, observational clinical study of pre-post comparison

Table I: Baseline features (contd.)

Family income status §	
§ Low	**25 (56.8)**
§ Medium to affluent	**19 (43.2)**

Δ Continuous data presented as mean ± standard deviations; § Categorical data presented as absolute values and percentages

design was conducted on 44 patients suffering from nasal polyps associated with CRS. SNOT-20 and EQ-5D-5L questionnaires were taken as the primary and secondary outcome measures respectively; assessed at baseline and after 3 months. Individualized homoeopathic medicines were prescribed on 'totality of symptoms.' Complete regression of polyps was achieved in 23 (58%) cases. Statistically significant improvements were observed in both the outcomes over a period of 3 months. Thirteen individualized homoeopathic medicines were prescribed. Out of those, Psorinum [n=11; 27.5%] was the most frequently prescribed medicine. Individualized homoeopathic medicines seemed to be promising treatment for symptomatic nasal polyps.

The methodological strengths of the study included the prospective patient enrolment and use of standardized and already validated outcome scales – SNOT-20 and EQ-5D-5L questionnaires. This study is representative of individualized homoeopathy only. In a broader interpretation of the law of similar, medicines were selected on the basis of 'totality of symptoms.' Observational trials are important for establishing hypothesis and the sample size for significant result. Though the sample size of this study was small, still was adequately powered to detect changes in the specified outcome measure over 3 months. The sample size had to be kept small keeping in mind the feasibility issues and stipulated time frame of postgraduate thesis. All the collected data (hard form) was converted into an analyzable and reproducible master chart (soft copy) where all data was extracted systematically and underwent statistical analysis subsequently.

At the end of the study, forty protocol-compliant

Table II: Changes in outcomes over time: analysis by Wilcoxon signed rank test (N=44)

OUTCOMES	BASELINE	AFTER 3 MONTHS	Z SCORE	P VALUE
	MEDIAN (IQR)	MEDIAN (IQR)		
SNOT-20 score	**33.5 (25.5 to 47.0)**	**16.5 (13.3 to 22.0)**	**-5.472**	**< 0.001**
EQ-5D-5L:				
§ Questionnaire score	**5.0 (3.0 to 6.0)**	**3.0 (2.0 to 5.8)**	**-2.844**	**0.004**
§ VAS score	**60.0 (50.0 to 70.0)**	**74.0 (62.0 to 81.8)**	**-5.528**	**< 0.001**

Table III: Changes in outcomes over time: pair-wise analysis by post hoc paired t test (N=44)

OUTCOMES	BASELINE;	AFTER 3 MONTHS;	CHANGE (0-3 MO);
	MEAN ± SD	MEAN ± SD	MEAN ± SD (95% CI)
SNOT-20 score	**37.0 ± 16.3**	**18.5 ± 7.7**	**18.5 ± 14.2 (14.2 to 22.9) §**
EQ-5D-5L:			
§ Questionnaire score	**4.6 ± 2.5**	**3.6 ± 2.6**	**1.0 ± 2.4 (0.3 to 1.8) ψ**
§ VAS score	**58.0 ± 14.0**	**72.8 ± 12.5**	**14.8 ± 9.6 (11.9 to 17.7)***

*§t43 = 8.660, P < 0.001 (significant); ψt43 = 2.831, P = 0.007 (significant); *t43 = 10.211, P < 0.001 (significant)*

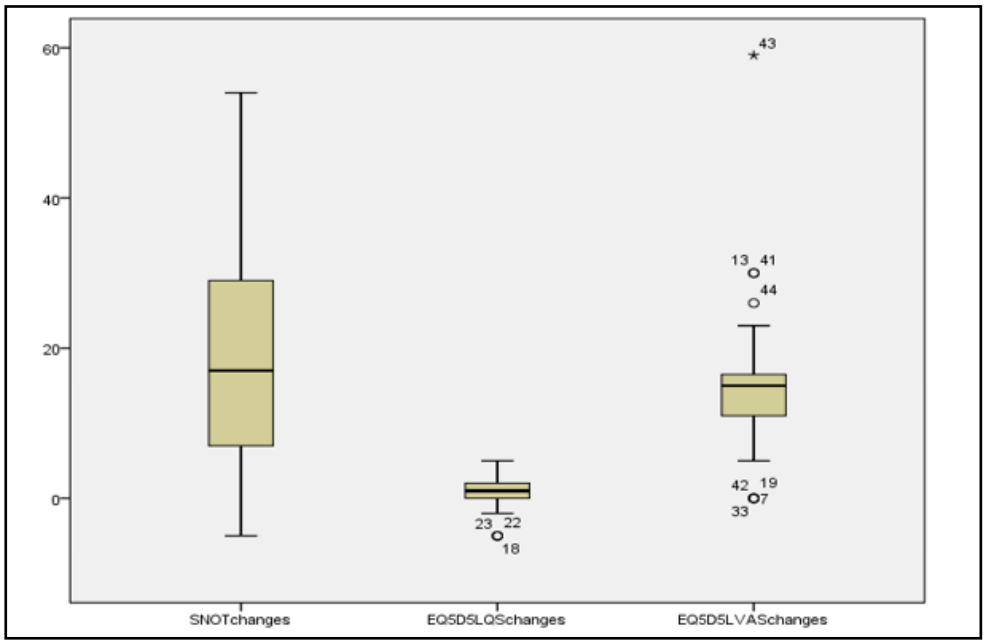

Fig. 2. Box and whisker plots showing changes in SNOT-20 scores, EQ-5D-5L questionnaire scores and EQ-5D-5L VAS scores over 3 months of treatment (N=44); SNOT-20 changes: Median 17.0, IQR 7.0 to 29.0; EQ-5D-5L questionnaire score changes: Median 1.0, IQR 0.0 to 2.0; EQ-5D-5L VAS score changes: Median 15.0, IQR 11.0 to 16.8

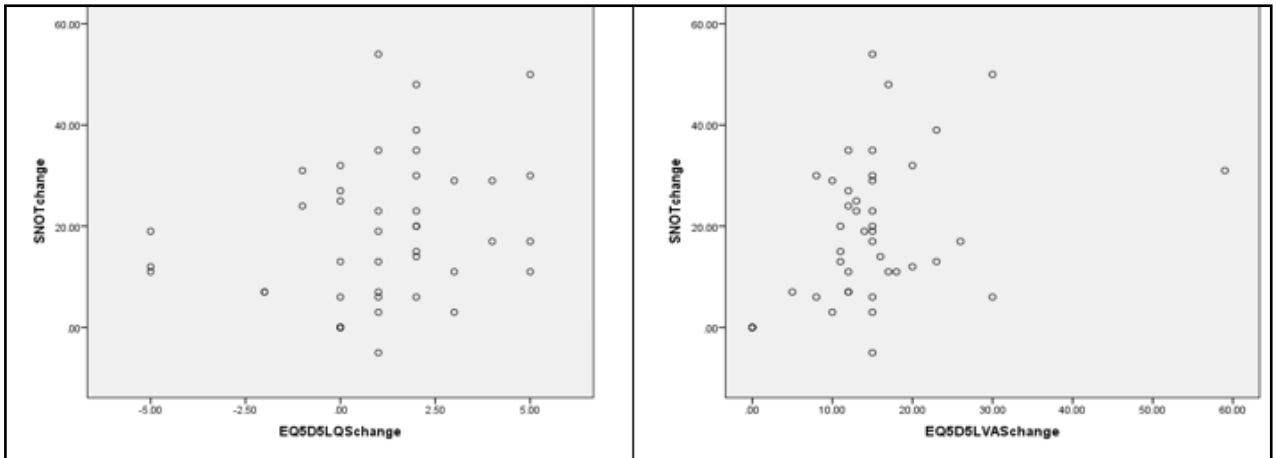

Fig. 3: Correlation scatter plot between changes in SNOT scores and EQ-5D-5L questionnaire score; Pearson's $r = 0.260$, $P = 0.088$

Fig. 4: Correlation scatter plot between changes in SNOT scores and EQ-5D-5L VAS measure; Pearson's $r = 0.385$, $P = 0.010$*

Figs. 3 and 4. Correlation statistics between changes in outcomes

Table IV: Used medicines

PRESCRIBED MEDICINES	NO. OF PRESCRIPTIONS	PERCENTAGES (%)
Tuberculinum	2	5
Thuja occidentalis	1	2.5
Sulphur	2	5
Sangunaria canadensis	1	2.5
Pulsatilla nigricans	2	5
Psorinum	11	27.5
Nitric acid	2	5
Natrum muriaticum	1	2.5
Hepar sulphuris	3	7.5
Dulcamara	10	25
Calcarea carbonica	5	12.5
Belladonna	1	2.5
Arnica montana	1	2.5

patients entered into the final analysis. Descriptive statistics was used to represent baseline data. Inferential statistics was used in terms of paired t test. Statistically significant improvements were observed in both the outcomes – SNOT-20 scores and EQ-5D-5L questionnaire scores. Statistically significant improvements were observed in both the outcomes. There was no violation of routine homoeopathy practice and the outcome data was gathered at baseline and 3 months of treatment. All the medicines were prescribed in fifty millesimal potencies. Homoeopathic medicines provided promising aid in treatment of symptomatic nasal polyps.

Constraints in sample size and duration of follow-up were the major limitations of the study. This study did not support conclusions as to the efficacy or effectiveness of the homoeopathic medicines because no methodology for this purpose (control group, randomization, blinding, etc.) was built into its design. Another limitation was inherent in the observational design of the study, i.e. the trial was open; no blinding was used. Thus, patient selection bias, evaluation bias, and data analysis bias might have affected the outcomes of the study. No causal inference could be attributed to the treatment and the treatment could not be regarded as the sole reason for the changes in the patients. Also, the other limitation was to use the subjective measures, namely SNOT-20 and EQ-5D-5L questionnaires, that might have incorporated some kind of bias.

Validity and reliability of the translated Bengali version of SNOT-20 questionnaire remain to be addressed formally in future studies. The data may also be helpful in the planning of further controlled research in homoeopathy. It would require specific objective measures for valid assessment and a longer observation period. Further independent replications and explorations by randomized trials with enhanced methodological rigor are warranted.

Conclusion

In this prospective, open, non-randomized, single arm, observational clinical study of pre-post comparison design conducted on 44 patients suffering

from symptomatic nasal polyps revealed complete regressions of polyps in 23 (58%) cases and statistically significant improvement in both SNOT-20 and EQ-5D-5L questionnaires after 3 months of individualized homoeopathic treatment. Further explorations by randomized trials are warranted.

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A Correlative Study between Chronic Tonsillitis and Helicobacter Pylori

Abhishek Singh,[1] Santosh Uttarkar Pandurangarao,[1] Aravind Darga Ramchandra,[1] Sridurga Janarthanan [1]

ABSTRACT

Introduction

Chronic tonsillitis is characterized by persistent inflammation of the palatine tonsils and seen commonly in patients attending ENT OPD. Bacterial infection is usually the cause but anaerobes and viruses may also be implicated. The possibility that tonsillar tissue possesses Helicobacter pylori or that H. pylori can colonize the palatine tonsils is explored.

Materials and Methods

Hundred patients aged between 5-50 years of either sex diagnosed with chronic tonsillitis undergoing elective tonsillectomy and willing to participate in the study were selected. Informed and written consent was taken from all the patients (in case of minor patients, consent was taken from parents). Specimen (tonsillar tissue) was harvested from the surgically removed tonsils and put through Rapid urease test. The results were analysed statistically using Chi square test and Unpaired t test and inference was drawn.

Results

Amongst 100 patients, 61 (61%) patients were females and 39 (39%) patients were males. Helicobacter pylori could be detected in Chronic Tonsillitis in 64 (64%) patients.

Conclusion

According to our study, Helicobacter pylori was found to be a common finding in cases of chronic tonsillitis. Even after regular treatment with antibiotics, the chances of getting acute infection in chronic tonsillitis still persist. We can try treatment for H. pylori and look for changes in recurrence of tonsillitis and also it can be tried in patients who are not willing/fit to undergo tonsillectomy.

Keywords

Palatine Tonsil, Tonsillitis, Tonsillectomy, Urease, Helicobacter pylori

Tonsils are components of mucosa associated lymphoid tissue (MALT), which protect vulnerable mucosal surfaces.[1] They are located in the tonsillar fossae between the anterior and posterior pillars formed by palatoglossus and palatopharyngeus muscles and the overlying folds of mucosa.[2] They are a part of the Waldeyer's ring, a complete circle of lymphoid tissue surrounding the entrance to the gastrointestinal and respiratory tracts along with the lingual tonsils, the adenoids and the diffuse aggregates of pharyngeal submucosal lymphoid tissue.

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In health and disease, the organisms cultured from the tonsils are extremely variable, with recognized differences in bacterial flora retrieved from surface and from core samples. Group A beta haemolytic streptococcus (GABHS) is the most commonly identified organism from the surface of the tonsil.[2] Up to 40% of asymptomatic individuals will also have a culture positive for this organism.[2] Other surface organisms include Haemophilus, Staphylococcus aureus, alpha haemolytic streptococci, Branhamella sp., Mycoplasma, Chlamydia, various anaerobes and a variety of respiratory viruses.[2] In recurrent tonsillitis, the samples grew a range of organisms but predominant were Haemophilus influenzae and S. aureus. A mixed flora was also common.

Chronic tonsillitis is a common condition characterized by persistent inflammation of the palatine tonsils, and bacterial infection is usually the cause. There are chronic

low grade symptoms affecting patient quality of life because of throat discomfort, and the production of white or yellow debris from the tonsillar crypts. Also, the patients have a feeling of low-grade ill-health. In children, historically, a very wide range of ailments including recurrent abdominal pain, general ill-health, failure to thrive and low body weight have been attributed to chronic tonsillitis. Conversely, removal of the tonsils has been claimed to result in increased growth rate and improvement in general health.

The gram negative bacterium Helicobacter pylori (H. pylori) resides in the human stomach, which was formerly considered a sterile environment due to its low pH. Helicobacter pylori have been argued to be the commonest chronic bacterial infection in man. It has been detected in the mouth, in dental plaque and, more recently, in human faeces.[1] Permanent H. pylori infection is often acquired early in life. H. pylori, implicated as an etiological factor in duodenal ulcers and gastritis, induces the appearance of lymphoid aggregates (MALT) in the stomach. This organism is cytotoxic via a nitric oxide synthesis cascade. The possibility that tonsillar tissue possesses H. pylori or that H. pylori can colonize the palatine tonsils is explored.

Rapid urease test is a preferred method of examining tissue as it has high sensitivity and specificity.[3] H. pylori produce urease, a hydrolase whose presence leads to any color change. The test well is filled with a urea containing gel and this is where the tonsillar tissue is inoculated and allowed to incubate. Urease produced by H.pylori will hydrolyze the urea in the gel. This will lead to accumulation of ammonium ion which causes a rise in the pH and this is detected by the pH indicators by a color change from yellow to pink or red.[3]

Materials and Methods

Data for this study was collected from the patients attending ENT outpatient department during the period from August 2017 to June 2018.

100 patients of either sex between 5 to 50 years of age diagnosed with chronic tonsillitis undergoing elective tonsillectomy under general anaesthesia and willing to participate in the study were selected. Informed and written consent was taken from all patients or their parents as applicable.

Tonsillectomy was done with dissection method and one tonsil per patient was collected. A 2 mm gross specimen was washed with normal saline. The specimen was then cut using a sterile blade and harvested. Specimen was then placed in a test well containing RAPID UREASE (GASTRO CURE SYSTEM RUT DRY TEST Batch No. A1060) and an initial color read at 0 min. Subsequent color changes were read at 30 min, 6 hour and 24 hours. Any color change from the initial yellow color to either pink or red was recorded as positive. Any test well that remained yellow after 24 hours was recorded as negative. No readings were taken after 24 hours. All the data was recorded in proforma.

Statistical analysis: Qualitative data was represented in the form of frequency and percentage. Association between qualitative variables was assessed by Chi square test and Unpaired 't' test. A 'p' value of less than 0.05 was considered statistically significant. Statistical analysis was done with IBM SPSS Version 22 for windows.

Results

The study was done on 100 (n=100) patients diagnosed with chronic tonsillitis.

The patients of age range 5 - 50 years and of either sex were studied. Youngest patient was 5 years old with the oldest being 46 years. Mean age was 16.24 years. (Table I)

Most of the patients were between 5-10 years (38%) and the least between 40-46 years (5%). (Fig. 1)

Amongst 100 patients who underwent tonsillectomy, 61 (61%) were female and 39 (39%) were male (Fig. 2).

100 (100%) tonsillar specimens were subjected to RUT, out of which 64 (64%) samples were found positive showing color change from initial yellow to pink/red within 24 hours and 36 (36%) samples showed no color change i.e. tested negative (Table II)

On considering the results within individual age groups, most number of positive cases i.e. 26 (68.42%) out of 38 (100%) were found in age group of 5-10 years. This was compared within age groups and found to be

Table I: Age distribution

HEARING GAIN	
n	**100**
Mean	**16.24**
Std. Deviation	**11.51**
Minimum	**5.00**
Maximum	**46.00**

statistically insignificant. (Table III)

RUT was positive in 40 (65.57%) out of 61 (100%) females and in 24 (61.53%) out of 39 (100%) males. This was compared using Chi Square test and found to be statistically insignificant. (Table IV)

Amongst 100 (100%) cases 64 (64%) tested RUT positive and 36 (36%) tested negative. When this was analysed through an Unpaired 't' test, it was found to be statistically significant ($p<0.04$). Helicobacter pylori could be attributed to Chronic Tonsillitis.

Discussion

Skinner et al in their study on 50 patients found that H. pylori seropositive patients showed higher expression of positively staining macrophage and thus may have huge implication for tonsillar immune response.[1]

The current study compares with Ochung'o et al who studied 39 children who were diagnosed with chronic tonsillitis of which 21 were male while 18 were female. 38.5% were found to be positive for H. pylori using RUT.[3] Our studies overall prevalence rate was found to be higher than this study.

A study by Siupsinskiene et al on 97 patients divided patients into 2 groups, with chronic tonsillitis (n=62) and with tonsillar hypertrophy (n=35;control group). They found incidence of H. pylori was higher in the first group (56.5%) as compared to the control group (31 .4%).[4] This was in accordance to our study suggesting prevalence of H. pylori in chronic tonsillitis is higher.

On comparing the current study with that of Aslan, et al,[5] who out of 52 patients found RUT positive in 22 (42%) of excised mucosal tissue and 24 (47%) of excised core tissue, our study results showed similar results.

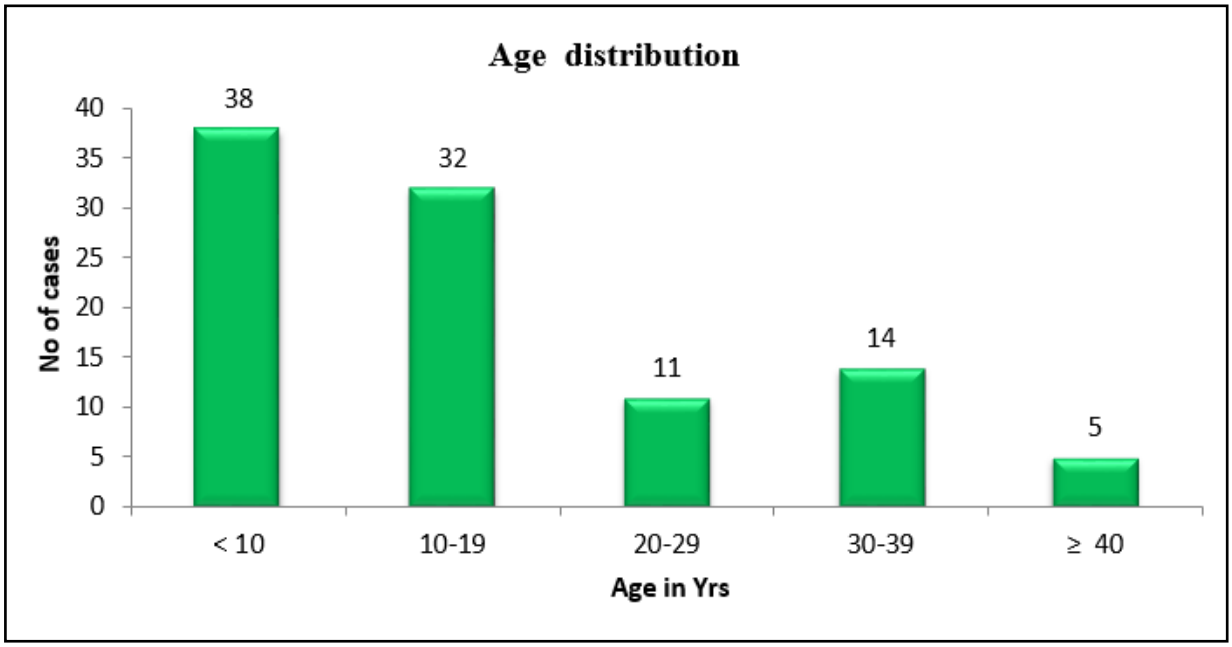

Fig. 1. Age distribution

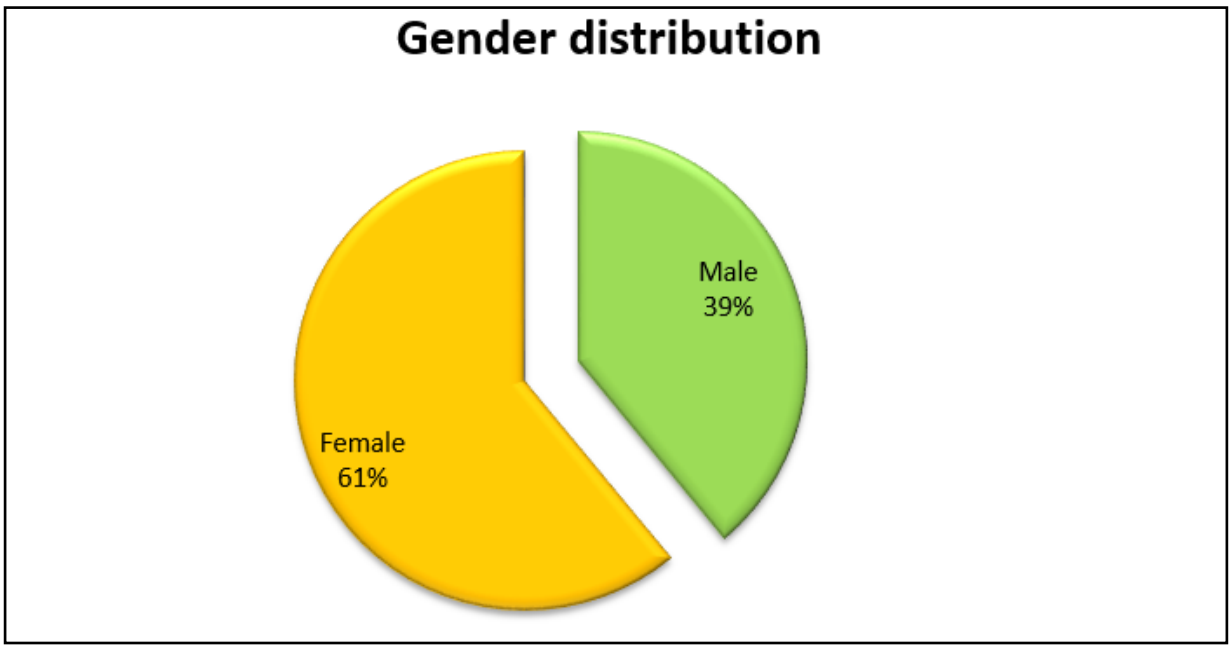

Fig. 2. Gender distribution

Table II: Results of RUT

H. PYLORI (RUT)	FREQUENCY	PERCENT
Positive	64	64.0
Negative	36	36.0
Total	100	100.0

Table III: Age distribution of RUT positive cases

AGE (IN YEARS)	H. PYLORI (RUT)		CHI SQUARE TEST
	POSITIVE (N=64)	NEGATIVE (N=36)	
<10	26	12	7.26 p=0.122
10-19	21	11	
20-19	9	2	
30-39	7	7	
≥ 40	1	4	

Table IV: Sex-wise distribution of RUT positive cases

AGE (IN YEARS)	H. PYLORI (RUT)		CHI SQUARE TEST
	POSITIVE (N=64)	NEGATIVE (N=36)	
Male	24	15	0.168 p=0.685
Female	40	21	

Conclusion

According to our study, Helicobacter pylori was found to be a common association in cases of chronic tonsillitis. It's suggested that tonsillectomy may protect the host against Helicobacter pylori infestation of the stomach. Therefore, it is plausible that Helicobacter pylori induces a pro-inflammatory reaction that is both local and systemic including in MALT tissue of Waldeyer's ring. Even after regular treatment with antibiotics the chances of getting acute infection in chronic tonsillitis still persists. Colonization of the human palatine tonsils by H.pylori is a potentially exciting new frontier which could radically alter the management approach to chronic recurrent tonsillitis. We can try treating for H. pylori and look for any changes in incidence of tonsillitis.

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Ethical Standards:

"The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional guidelines on human experimentation (IEC Registration No- ECR/731/Inst/KA/2015 issued under rule 122DD of the Drugs & Cosmetics Rules 1945, Ref No- JJMMC/IEC/41-2017) and with the Helsinki Declaration of 1975, as revised in 2008."

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Benefit of Tympanoplasty with or without Cortical Mastoidectomy in Active Mucosal Otitis Media – A Comparative Study

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ABSTRACT

Introduction

Chronic otitis media (COM) is amongst the most common diseases treated by ENT surgeons in India. It has been advocated in lot of research articles that there is no significant difference in tympanoplasty done in active and inactive COM. The objective was to see if cortical mastoidectomy in cases of active mucosal COM, improves the success rate of tympanoplasty measured as per the following parameters: improvement in the hearing threshold by 15 dB, increased graft uptake and reduction in retraction of tympanic membrane in post operative period.

Materials and Methods

This study comprises of 120 patients coming to the ENT OPD from October 2016 to October 2017 with active mucosal COM with central perforation requiring tympanoplasty. These patients were randomly assigned to two groups: Group 1 of 60 subjects in which tympanoplasty without mastoidectomy was done, Group 2 of 60 subjects in which tympanoplasty with mastoidectomy was done. Patients were evaluated after a post operative period of 3 months.

Results

The Results were the hearing improvement was 73.33% in group 1 while 83.33% in group 2, graft uptake was 63.33% in group 1 and 80% in group 2, graft retraction was 33.33% and 23.33% in group 1 and group 2 respectively.

Conclusion

There was statistically significant difference in results in group with and without mastoidectomy in active mucosal chronic otitis media with respect to graft uptake and improved hearing.

Keywords

Tympanoplasty; Otitis Media, Suppurative; Mastoid

Chronic Otitis Media (COM) is defined as chronic infection confined to the middle ear mucosal cleft which comprises the eustachian tube, mesotympanum, aditus and mastoid air cells. Clinically, there are two varieties of COM, mucosal and squamous. Chronic suppurative otitis media is amongst the most common diseases for the patients coming to ENT surgeons in India. Tympanoplasty is thus one of the routinely performed surgeries by the ENT surgeons. It is a commonpractice among the otolaryngologists to usually wait for the ear to become inactive before performing tympanoplasty. However, a lot of research papers have been published suggesting no added advantage of an inactive ear over an active ear for better results of the surgical procedure.[1,2,3]

Cortical mastoidectomy is generally performed in mucosal COM to clear the atticoantral block, if present, and achieve aeration of the mastoid. Aeration of the mastoid has been believed to be one of the very important factors in achieving better results of tympanoplasty in terms of graft uptake and hearing improvement. The use of mastoidectomy as a means to re-establish drainage

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of mastoid antrum in safe or non-cholesteatomatous chronic suppurative otitis media is still controversial.[4]

This study was designed to assess the effectiveness of cortical mastoidectomy in cases of active mucosal COM. We wanted to evaluate if aerating the mastoid by simple cortical mastoidectomy in cases of active mucosal COM improves the success rate of tympanoplasty measured as per the following parameters: Improvement in the hearing threshold by 15 dB measured by pure tone audiometry,increased graft uptake and reduction in retraction of tympanic membrane in post-operative period.

Materials and Methods

This study comprised 120 patients coming to the ENT OPD from Oct. 2016 to Oct. 2017 with active mucosal COM and central perforation requiring tympanoplasty. These patients were randomly assigned to two groups by simple randomization method - Group 1 of 60 subjects in which tympanoplasty without mastoidectomy was done and Group 2 of 60 subjects in which tympanoplasty with mastoidectomy was done. All the patients were provided with thorough explanations about both the surgical techniques and signed an informed consent before enteringthe study. The patients were explained about the risk involved in operating in active disease and risks involved in doing cortical mastoidectomy.

Inclusion criteria:

Patients with active or wet ear

Moderate, large, subtotal central perforation

Age more than 14 years

Unilateral or bilateral disease

Exclusion criteria:

Patients having otomycosis

Revision surgery

Patients having focal infective sources like nose and paranasal sinuses infection, DNS,tonsillitis etc.

Patients refusing consent to be included in the study

All the patients underwent routine ENT and pre-anaesthetic evaluation. Puretone audiometry and impedance audiometry were conducted in all patients in preoperative and postoperative periods(after 3 months). Eustachian tube functional assessment was done using Toynbee test (impedance audiometry). Suction clearance and otoscopic findings were confirmed under microscope. Discharge was sent for culture and sensitivity. X-ray mastoids were taken in both groups.

Surgery was done under local or general anaesthesia as per the convenience of the patient, using post-aural incision and underlay technique. In Group 1, tympanoplasty without mastoidectomy was undertaken and in Group 2, tympanoplasty with cortical mastoidectomy was done along with widening of the aditus and antrum. Thorough removal of the mastoid cells was attempted to reduce the air cells that could act as infection nidus. Type of tympanoplasty was type 1 or type 3 with or without ossiculoplasty depending on intra operative finding and pre-operative hearing threshold. Temporalis fascia graft was used. Sutures were removed on the 7th day post-operatively.

In the postoperative period assessment of the graft was done - overall uptake of graft (100% or not) after 3 months, hearing threshold by pure tone audiometry after 3 months and retraction of the tympanic membrane(present or not) using impedance audiometry after 3 months.Data regarding the preoperative work up, operative technique and assessment during follow-up were entered in a specially prepared proforma.

Results

A comparative surgical evaluation study was done consisting of 120 patients of active mucosal COM,60 underwent tympanoplasty without mastoidectomy, while another 60 underwent tympanoplasty with mastoidectomy.

In our study 46 % individuals were in the age group of 14-30 years and 31-50 years respectively in Group 1, while 43% and 50% were in the above age group in Group 2. Patients above the age of 50 years comprised 2.8% in both the groups. The male patients were 36 and 38 in Groups 1 and 2 respectively while female patients were 24 and 22 in Group 1 and 2 respectively. The male to female ratio was 3:2 in Group 1 and 3.2:1 in Group 2. The ratio of unilateral to bilateral was 2.75:1 in Group 1, while 3.28:1 in Group 2. The size of perforation in

Table I: Preoperative hearing threshold

PREOP HEARING	GROUP 1	GROUP 2
<20 dB	-	-
20-35 dB	38	36
36-50 dB	14	20
>50 dB	8	4
Total	60	60

Group 1 was 26 moderate, 24 large and 10 subtotal while in Group 2 was 32 moderate,16 large and 12 subtotal. The percentage of moderate, large and subtotal perforation in Group 1 was 43.33%,40%,16.66% and in Group 2 was 53.33%,26.66%, 20% respectively. The preoperative hearing threshold was between 20-35 dB in Group 1and 2 was 63.3% and 60%. (Table I)

The patients in both the groups underwent type 1 and type 3 tympanoplasty.

The percentage of patients who underwent type 1 tympanoplasty was 70% and 73.33% ,while those who underwent type 3 tympanoplasty was 23.33% and 26.66% respectively in Group 1 and Group 2. The improvement in the hearing threshold was73.33% in Group 1 and 83.33% in group 2. (Table II)

The postoperative graft uptake was 63.33% in Group1 and 80% in Group 2. (Table III) The post operative retraction was present in 33.33% in Group 1 and 23.33% in Group 2. (Table IV)

In the patients with bilateral disease graft uptake in Group 1 was 62.5% and in Group 2 was 85.71%,while hearing improvement was 62.5% in Group 1 and 85.7% in Group 2. (Table V)

Discussion

This is a study of 120 patients in which 120 ear surgeries were performed with age greater than 14 years. Eighty percent patients belonged to lower socioeconomic status, 15% were in middle economic strata while 5% belonged to upper socioeconomic strata.

Temporalis fascia was used as graft material in both the groups. Of all the graft materials, temporalis fascia has become most popular and standard to which all others are compared.[5] Patients underwent type 1 or type 3 tympanoplasty (with or without ossiculoplasty) depending on the preoperative hearing loss and intra-operative finding. Patients were evaluated after a post-operative period of 3 months. Post-operative assessment was done under the following parameters: Hearing threshold, Graft uptake and Presence of retraction.

In our study mean age was 35.3 and 32.8 years in Group 1 and Group 2 respectively. Age of the patients was not found to have any direct effect on the post-operative results. According to Adkin et al, age has no significant bearing on success.[6] Similarly Emmet studied 260 cases and concluded in his study that age is not a factor in success or failure of healing following tympanoplasty.[7]

The post-operative result was analysed under the following parameters -1) Assessment of the hearing threshold: After postoperative period of 3 months, improvement in the hearing threshold of greater than 15 dB was observed in 73.33% in Group 1, while 83.33% patients in Group 2 showed improvement.Thus improvement in the hearing threshold of greater than 15 dB was more in patients in which tympanoplasty was done with mastoidectomy. The difference between the two was statistically significant. Balyan et al, in their study on of 323 patients, observed no statistically significant difference in hearing outcome between those who underwent type 1 tympanoplasty with or without mastoidectomy.[8] In the study by Mishiro et al the rate of post-operative air bone gap within 20 dB were 81.6% in group with mastoidectomy and 90.4 % in group without mastoidectomy without a statistically significant difference.[9] In another study on 120 subjects, hearing gain was 75% of subjects in both the groups. This study concluded that it might be a good practice to open the mastoid antrum and the air cells if the middle ear mucosa was unhealthy.[10] Some other studies reported varying results.[11,12,13] Nayak et al reported better hearing gain with concomitant cortical mastoidectomy with myringoplasty and a higher success rate as compared to myringoplasty alone.[14] But all these studies were

Table II: Postoperative hearing improvement

POST OPERATIVE HEARING IMPROVEMENT	GROUP 1	GROUP 2	CHI SQUARE	P
Improved(>15 dB)	44	50	1.76	0.184
Not improved	16	10		
Total	60	60		

Table III: Postoperative graft uptake

GRAFT UPTAKE	GROUP 1	GROUP2	CHI SQUARE	P
Uptake	38	48	4.1	0.043
Failure	22	12		
Total	60	60		

Table IV: Postoperative retraction

POST OPERATIVE RETRACTION	GROUP 1	GROUP 2	CHI SQUARE	P
Absent	40	46	1.47	0.22
Present	20	14		
Total	60	60		

Table V: Bilateral disease assessment

BILATERAL DISEASE	GROUP 1	GROUP 2	CHI SQUARE	P
Graft uptake	10/16	12/14	2.05	0.15
Hearing improvement	10/16	12/14	2.05	0.15

undertaken in wet and/or dry ear. In our study with wet active discharging ear, we found that there were better results in cases in which cortical mastoidectomy was done although the difference was not statistically significant.

Assessment of graft uptake was undertaken after postoperative period of 3 months. The overall graft uptake was found to be 63.33% in Group 1 and 80% in Group 2. Thus, graft uptake was 15% better in patients in which tympanoplasty was done with mastoidectomy. However the difference between the two was not statistically significant. Balyan et al found no statistically

significant difference in graft take rate in Tympanoplasty with or without mastoidectomy.Thus he concluded that aerating the mastoid may improve the success rate of the surgery in revision cases.[8] In the study by McGrew et al on 484 patients of untreated tympanic membrane perforations, the adjusted rate of subsequent procedures were 15.5% in Tympanoplasty group and 12.2% in Tympanoplasty with mastoidectomy group respectively. They concluded that mastoidectomy was not necessary for successful repair of the tympanic membrane.[15] Similarly Mishiro et al reported graft uptake rate of 90.5% in Tympanoplasty with mastoidectomy and 93.3% in Tympanoplasty without mastoidectomy.[9] Krishnan et al found 82.5% graft uptake was in patients with Tympanoplasty without mastoidectomy and 100% in patients with tympanoplasty and mastoidectomy.[10] Bhatt et al also concluded that there was no statistical difference in groups with or without mastoidectomy.[11] Thus, tympanomastoidectomy was not found to be superior to Tympanoplasty over short term follow-up.[12,13,16]

In a 6 month follow-up study, 100 % graft uptake was reported in patients with Tympanoplasty with mastoidectomy and 60% in patients with tympanoplasty without mastoidectomy.[14] This study suggested that in small and sclerosed mastoid, it is desirable to do cortical mastoidectomy even if the ear is dry to create a mastoid air reservoir which probably can buffer the detrimental effects of a poorly functioning Eustachian tube. This view was also expounded by Jackler and Schindler in a previous article.[17] They found the results to be logical and opined that the surgeries by well-trained surgeons over certain durations of time may possibly give better results in group 2.[17] However, in our study with active discharging ear, there were 15% better results in group in which Tympanoplasty with mastoidectomy was done.

Assessment of graft retraction after post-operative period of 3 months: Retraction of the tympanic membrane was found to be 33.33% in group 1 while 23.33% in group 2. Thus, the retraction of the tympanic membrane was noted to be 10% more in group in which Tympanoplasty was done without mastoidectomy; however, the difference between the two was not statistically significant. Wehrs and Tulsa thought that aeration of mastoidectomy cavity was important to prevent retraction pockets and ensured an adequate air reserve.[18] In the study by Krishnan et al, 20% of the patients in dry ear group developed retraction of the tympanic membrane after tympanoplasty without mastoidectomy.[10] Blockade of the aditus to antrum was found in 18 cases out of 30 in Group 2. The postoperative hearing outcome and graft uptake was better in group 2 by 10% and 15% than in group 1.

In our study, the patients with bilateral disease had slightly less success rate than unilateral disease in both Group 1 and Group2. Graft uptake and hearing improvement was 62.5% and 85.71% in Group 1 and 2 respectively. Group 2 had 23% better results than Group 1. The reason for this may be creation of a better reservoir of air by mastoidectomy. Bilateral disease represents a common persistent and severe pathology like eustachian tube blockade, dysfunction and allergy. Hence bilateral disease has been hypothesized to have worse outcome. Albu et al, Pinar et al and Albera et al also reported that patient with contralateral ear disease were associated with lower success rate.[16,19,20] Ashok et al found lower success rate (66%) in presence of bilateral perforation.[21]

In our study the graft uptake for moderate, large and subtotal perforation was 79.31%, 75.00% and 63.63% respectively. Thus post operative results, related to the size of the perforation, were better in smaller sized perforations. In the study by Adkins et al, there was a definite relationship between the size of perforation and likelihood of success.[6] There is still a controversy as to whether the size influences the success rate. According to Webb et al, perforation size ($p=0.11$) was not significantly related to success rate.[12] Some other studies also could not relate the success rate of tympanoplasty with tympanic membrane perforation size.[16,19,20] With increased technical difficulty and larger area, which must vascularise and epithelialize with bigger perforation, surgical failure would not seem unexpected.

Thus with respect to all the three parameters described above, i.e., post-operative hearing threshold, graft uptake and reduction of retraction tympanic membrane in the postoperative period the results were better by 10-20 % with Tympanoplasty and mastoidectomy in a wet discharging ear.

Conclusion

There have been various research papers advocating no difference in results of operating active and inactive ear in chronic otitis media. We studied the advantage of concomitant cortical mastoidectomy in active mucosal COM. We found that results of surgery in terms of hearing threshold were numerically better in the group with Tympanoplasty with mastoidectomy than Tympanoplasty without mastoidectomy by 15%. Similarly graft uptake was better by 15% and postoperative retraction was less by 10% in the group with Tympanoplasty with mastoidectomy. The difference was statistically significant with respect to graft uptake but not with respect to hearing improvement and retraction of neotympanic membrane. Surgical improvement of aeration of mastoid, in our opinion, does have added advantage in tympanoplasty in active mucosal chronic suppurative otitis media.

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Relationship between the Recurrent Laryngeal Nerve and the Inferior Thyroid Artery in the Togolese Subject: Surgical Anatomy Study from 227 Thyroidectomies

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ABSTRACT

Introduction

Identification of the recurrent laryngeal nerve during thyroid surgeries is recommended to preserve its functionl integrity. This study aims to determine the relationship between the recurrent laryngeal nerves and the inferior thyroid arteries during thyroidectomies, as well as any particularities and intraoperative complications.

Materials and Methods

Observational cross-sectional study of all culturally Togolese patients who underwent thyroidectomy with nerve dissection in the ENT department of Sylvanus Olympio University Hospital from 1 January 2013 to 30 June 2017, i.e. a period of 4 years 6 months

Results

The sex ratio was 0.14 i.e., 7 women for 1 man and the average age of 41.82 years. Solitary nodules and multinodular goiters were the most operated lesions in 40.97% and 33.04%, respectively, with a plunging character in 17 cases. We had 306 cases of nerve dissection but the recurrent laryngeal nerve could not be found in 1 case on the right. It was globally retro-arterial (under the trunk and under the branches of the inferior thyroid artery) in 75.08% of cases with prevalence of the truncal, pre arterial situation in 16.07% and inter-arterial in 3.28% cases. The nerve was non-recurrent (type II pathway) in 1 case on the right. There was no recurrence injury. Parathyroid devascularization (5 cases) was autotransplanted. The surgeon's experience did not have a significant impact on the occurrence of intraoperative complications (p = 0.24).

Conclusion

This observational cross-sectional anatomical-surgical study supports the existing data on the relationships between the recurrent laryngeal nerve and the inferior thyroid artery by confirming their variability. Nevertheless, it was marked by the predominance of the retro arterial truncal situation of the nerve unlike the literature that most often reports a situation of the nerve under the arterial branches.

Keywords

Inferior Thyroid Artery; Recurrent Laryngeal Nerve; Thyroidectomy; Goiter; Togo

Recurrent injuries are very dreaded lesions during thyroidectomies because of the dysphonia or dyspnea they cause, wherein dyspnea may be life-threatening in case of bilateral damage. Recurrent paralysis constitutes, with hypocalcemia, the most frequent immediate postoperative complications of thyroidectomies due to the anatomic relationships of the gland with the recurrent laryngeal nerves (RLN) or lower laryngeal nerves and parathyroids.[1,2] Serious complications after thyroidectomy such as compressive hematoma and acute dyspnea by bilateral paralysis in closure have become rare, thus bringing to the fore lesions that were previously considered minor

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complications. Already in the sixth century, in the history of thyroidectomy, postoperative dysphonia by recurrent laryngeal nerve injury were recognised.[3] Responsibility for recurrent paralyses in several deaths after the first thyroidectomies promptly led to changes in the surgical technique by identifying the nerves intraoperatively or performing an intracapsular dissection, with some success. Over time, the anatomical and functional preservation of RLN has become the gold standard of thyroid surgery. Various artifices have been described but it seems that the essential rule is the respect of a careful, rigorous and standardized surgical technique including RLN identification.[2,4] Nerve tracing techniques have varied in recent years, from visual identification, through injection of blue dye in the inferior thyroid artery (ITA) to neuromonitoring. All in all, in practice, RLN tracking is guided by that of the ITAs. In sub-Saharan Africa, visual identification is the preferred technique of locating RLN as evident from the studies of Koumaré et al in Mali[5] and Ngo nyeki et al in Cameroon and Gabon.[6] Since thyroid surgery is one of the most frequent in otolaryngology (ENT)[7] and because of the effectiveness of the training of ENT specialists for four years now in Togo, it seemed appropriate to carry out this study whose general objective was to have data facilitating the identification of RLN in the Togolese subject.

Materials and Methods

Framework, population, type and period of study:

Our study was conducted as part of the ENT and cervico-maxillo-facial (CMF) surgery department of Sylvanus Olympio University Hospital (CHU S.O.) in Lomé. The lack of neuromonitoring device in the operating room of the said service should be noted. It was a cross-sectional observational study of all culturally Togolese patients who underwent thyroidectomy with dissection of RLN in the ENT and CMF Surgery department from January 1st, 2013 to June 30th 2017, i.e., a period of 04 years 6 months. Depending on the procedure, it could be one or both nerves at risk. A consent was signed by the patient before any thyroid surgery in our practice and inclusion in the study.

Selection criteria:

Included in our study were all patients who underwent thyroidectomy with RLN dissection in the department during the study period. Excluded from the study population were cases of surgical revision imposed by the malignant nature of the operated lesion, patients with a history of thyroidectomy, non-culturally Togolese patients (cultural nationality was selected based on the names borne, spoken language and verbal confirmation by the patient). We did not include in our study the cases of Isthmectomy alone.

Parameters studied:

We were interested in the demographics, the operated thyroid injury, the surgical procedure performed, the intraoperative findings and the relationship between the ITA and the RLN.

Analysis and data processing:

The data was captured and analyzed using the Epi-Info 7 Software and the results were formatted using Excel 2013. The frequency comparison of the categorical variables was done using the Pearson's chi-square test considering its conditions of validity and realization. The decisions were taken with a risk α of 5%.

Results

General aspects:

From January 1, 2013 to June 31, 2017, for a period of 04 years 6 months, 281 thyroidectomies were performed. Of these thyroidectomies, 227 (80.78%) were selected for this study, based on the selection criteria. Three hundred six nerve dissections were performed including 148 unilateral and 79 bilateral. The female sex was represented in 199 cases (87.67%) and the male sex in 28 cases (12.33%). The sex ratio was 0.14 i.e., 1 man for 7 women. The average age was 41.82 years with a standard deviation of 13.58 years and extremes of 12 and 83 years. The age group of 30 to 45 years was the most represented with 94 cases (41.41%). In 160 cases (70.48%), the intervention was performed by an experienced surgeon (ENT specialist and head and neck

surgeon) and in 29.52% of cases by a specializing doctor alone or under the supervision of a specialist circulating (observer).

Intraoperative findings and surgical aspects:

The nature of the thyroid lesion, determined preoperatively based on clinical and paraclinical examinations, was clarified intraoperatively. Tissue nodules and euthyroid multinodular goiters were the most common lesions with 93 cases (40.97%) and 75 cases (33.04%), respectively. A peculiar aspect of the gland was noted in 35 cases (15.42%) dominated by the plunging character with 17 cases. Other features were: haemorrhagic gland (11 cases), tumor infiltration of surrounding tissues (3 cases), hypertrophy of a parathyroid (2 cases) and tracheomalacia (2 cases). Relationship between the recurrent laryngeal nerve and the inferior thyroid artery (Figs. 1 and 2)

We had 306 cases of nerve dissection distributed 154 on the right and 152 on the left. The nerve could not be found on the right in 1 case; the procedure then being continued by dissection in contact with the gland until excision. The RLN was retro-arterial in 200 out of 305 nerves (65.57%) distributed between the left side (101 cases) and the right side (99 cases); it was globally retro-arterial (under the trunk and under the branches of the ITA) in 112 cases on the right on 153 nerves (73.20%) and 117 on the left (76.97%). RLN was globally pre-arterial in 49 cases (16.07%) and inter-arterial in 10 cases (3.28%). In 6 cases, the ITA was not found, 4 on the left and 2 on the right. The nerve was non-recurrent (Type II Pathway) in 1 case (right) and no further exploration to identify an associated asymptomatic malformation was made. RLN position variations with respect to gender-specific ITA were not statistically significant (Table I); those of the RLN compared to the ITA according to the diagnosis (Tables II and III) did not note a statistically significant difference on the right ($p = 0.74$) or on the left ($p = 0.56$).

Table I: RLN position variations in relation to ITA according to gender

	NUMBER		P-VALUE
	FEMALE	MALE	
Right retroarterial (crossing under the trunk)	85	14	0.6
Left retroarterial	88	13	0.99
Right prearterial (crossing over the trunk)	20	2	0.88
Left prearterial	21	3	0.76
Right interarterial (between branches)	8	0	0.59
Left interarterial	2	0	0.58
Under the branches on the right	10	3	0.44
Under the branches on the left	14	2	0.71
On the right branches	2	0	0.58
On the branches on the left	1	0	0.25
Parallel inside on the right	6	0	0.76
Parallel inside on the left	3	1	0.99
Other positions	7	2	0.68

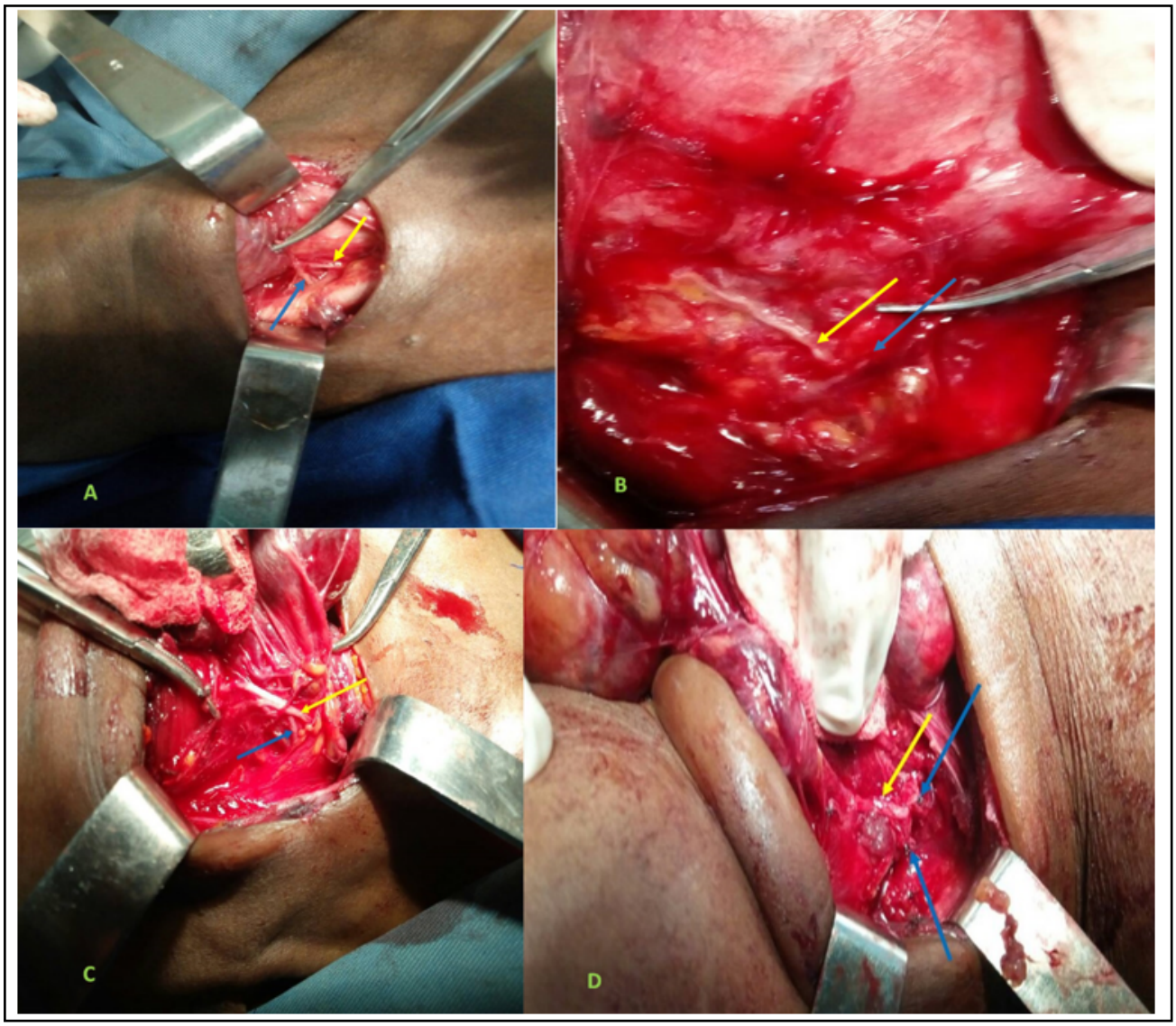

Fig. 1. Some relationships between the right RLN (yellow arrow) and the right ITA (blue arrow): retro arterial nerve (A and B); pre-arterial nerve (C); inter-arterial nerve (D) with ligated arterial branches.

Intraoperative complications

They were present in 8 cases (3.52%) including 1 case of sacrifice of the left RLN infiltrated by the tumor lesion. There has not been, strictly speaking, any recurrent nerve injury. Inadvertent parathyroid devascularization was noted in 5 patients, concerned the left lower parathyroid (3 cases), the right lower parathyroid (1 case) and the two right parathyroid ones in 1 case. Parathyroid auto transplantation was performed in these cases. Other complications were the tracheal rupture and a wound in the thoracic duct. Lymphatic leak occurred during a bilateral neck dissection (left radical and right functional) and was associated with total thyroidectomy. The tracheal rupture was made from the 2nd to the 4th tracheal ring at the junction of the cartilaginous (anterolateral) and non-cartilaginous (posterior) parts on the left side of the exterior of the mass of thyroid. The surgeon's experience did not have a significant impact on the occurrence of complications in this study ($p = 0.24$).

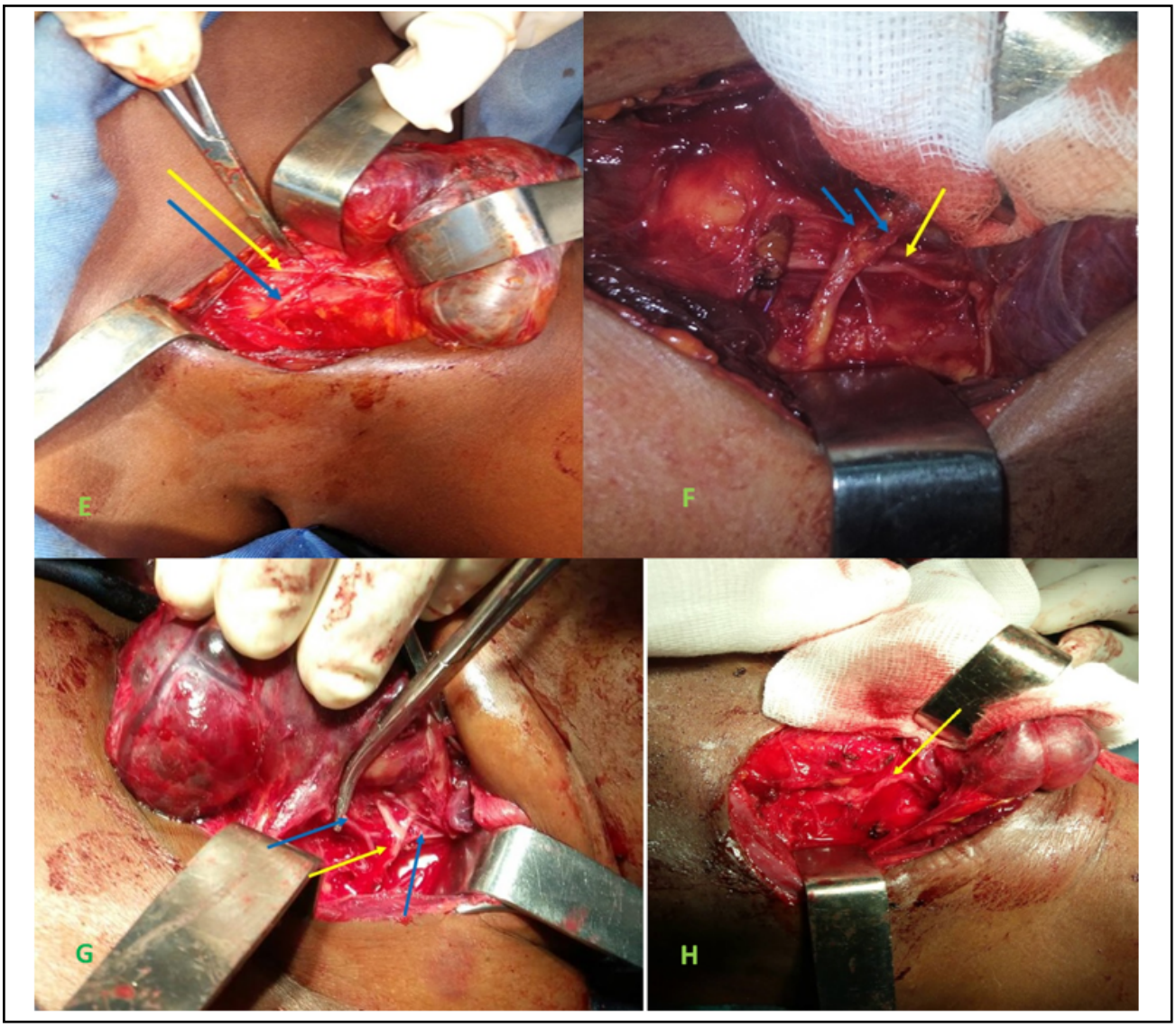

Fig. 2. Some relationships between the left RLN (yellow arrow) and the left ITA (blue arrow): retro arterial nerve (E); nerve under the arterial branches (F); inter-arterial nerve (G); ITA absent (H).

Discussion

Our study was an observational study on the relationship between the recurrent laryngeal nerve and the inferior thyroid artery in the Togolese subject. This study was made possible by the adhesion of all the surgeons to provide, as far as possible, the necessary information, thus allowing homogeneity in the collection of data. Indeed, although the search for RLN during thyroidectomy has been systematic in our practice for several years, the precision of the anatomico-surgical data on the nerve began with the present study.

Cases of surgical revision imposed by the malignant nature of the operated lesion and patients with a history of thyroidectomy were excluded from the study because of the anatomical changes that would have already led to an earlier exploration of the thyroid compartment. Also, postoperative inflammatory changes make dissections

Table II: Position variations of the right RLN relative to the ITA according to the diagnosis.

	RETRO ARTERIAL	PRE ARTERIAL	UNDER BRANCHES	INTER ARTERIAL	OTHER	TOTAL
Multinodular goitre	**39**	**9**	**9**	**3**	**4**	**64**
Basedow multinodular goitre	**3**	**1**	**0**	**0**	**0**	**4**
Simple goitre	**4**	**1**	**0**	**0**	**0**	**5**
Basedow disease	**21**	**2**	**0**	**1**	**1**	**25**
Cystic nodule	**2**	**0**	**0**	**0**	**1**	**3**
Mixed nodule	**2**	**2**	**2**	**1**	**1**	**8**
Tissue nodule	**26**	**7**	**2**	**3**	**5**	**43**
Malignant neoplasm of the thyroid body	**2**	**0**	**0**	**0**	**0**	**2**
Total	**99**	**22**	**13**	**8**	**12**	**154**

difficult, thus promoting the risk of nerve damage as reported by some authors.[2,8,9]

We considered cultural or sociological nationality based on the name borne, the language spoken by the patients and the verbal confirmation to include them as Togolese subjects. This procedure avoids consideration of legal or political nationality which, although legal, could include non-Togolese subjects who may have different anatomical particularities. Isthmectomy cases were not included in this study because it is an RLN-free intervention. The didactic aim of this study, the general objective of which was to have data facilitating the identification of RLN in the Togolese subject, explains the methodology applied in this work.

Several RLN positions have been reported, but overall, three types of positions come up frequently:[10,11]

- Globally retro-arterial nerve (under the trunk or branches of the ITA)
- Globally pre-arterial nerve
- Inter-arterial nerve

We summarize in Table IV some comparative aspects between our series and other anatomico-surgical studies (excluding cadaveric dissections) carried out on a given

Table III: Position variations of the left RLN relative to the ITA according to the diagnosis.

	RETRO ARTERIAL	PRE ARTERIAL	UNDER BRANCHES	INTER ARTERIAL	OTHER	TOTAL
Multinodular goitre	33	9	8	0	3	53
Basedow multinodular goitre	3	1	0	0	0	4
Simple goitre	3	0	1	0	1	5
Basedow disease	20	3	0	0	2	25
Cystic nodule	1	0	1	0	1	3
Mixed nodule	6	2	0	1	1	10
Tissue nodule	33	9	6	1	1	50
Malignant neoplasm of the thyroid body	2	0	0	0	0	2
Total	101	24	16	2	9	152

Table IV: Comparison between our series and other anatomico-surgical studies

AUTHOR AND YEAR	COUNTRY	NUMBER OF NERVES SEEN	UNSEEN NERVES	GLOBALLY RETRO-ARTERIAL NERVE		INTER-	OTHER
Our series	Togo	305	1	229 (75.08%)	49 (16.07%)	10 (3.28%)	17 (5.57%)
Zada et al[11] / 2014	Pakistan	398	18	138 (34.67%)	220 (55.27%)	40 (10.05%)	0
Calò et al[12]/ 2014	Italy	3422	0	84.13%	5.21%	5.50%	5.16%
Ngo Nyeki et al[6] / 2013	Gabon / Cameroon	62	0	36 (58.06%)	-	9 (14.52%)	17 (27.42%)
Page et al[13] 2003	France	403	0	244 (60.55%)	159 (39.43 %)	0	0
Koumaré et al[5] / 2002	Mali	1133	53	987 (87.11%)	146 (12.89%)	0	0
Sturniolo et al[14] / 1999	Italy	280	34	121 (43.21%)	87 (31.07%)	72 (25.71%)	0

NB: some ratios are calculated in the table from the authors' data.

population in order to identify any peculiarities.

This comparison confirms the variability of the RLN position relative to the ITA but a relative predominance of the retro-arterial position. The remarkable peculiarity is the low frequency of reports with arterial branches in our series compared to what is reported in the literature.[7,15] This brings us to the possibility of anatomical changes by the thyroid masses that are often bulky in our part of the world because of the delay in consultation, then pushing the retro and pre-arterial nerve towards the truncular part of the artery. The goiter often leads to much less predictable changes in the nerve situation, especially in cases of inferior polar nodules plunging into the upper orifice of the thorax.[4]

The visual identification of RLNs from ITAs allowed the identification of almost all nerves in our context thus confirming the use of this report as a method of choice in locating RLN alongside that using Zuckerkandl's tubercle (ZT), Berry's ligament and the tracheoesophageal groove. Classically, the RLN can be identified intraoperatively as a side of Simon's triangle which is formed by the common carotid posteriorly, the RLN anteriorly and the ITA as the base.[7] These other methods have limitations in the search for RLNs.

The use of ZT in locating is limited by its inconsistency and confusion in multinodular goiters with supra-centimetric nodules. The morphometric classification of ZT proposed by Pelizzo et al is as follows:[16]

- Grades 0 and 1, the tuber is practically undetectable or reduced to a slight glandular mound;
- Grade 2 corresponds to a tuber whose large diameter is less than 1 cm;
- Grade 3 corresponds to a tuber of more than 1 cm.

It is therefore clear that only grades 2 and 3 of ZT assist in locating RLNs. In Togo, in a series of 48 patients, James et al did not find ZT in more than half of patients (56.21%).[17]

The use of the Berry ligament, which is a thickening of the Gruber's thyroid tracheal ligament attaching the posteromedial edge of the thyroid gland to the cricoid cartilage and to the 1st and 2nd tracheal rings most often encounters bleeding, characteristic of this area with a risk of injury to the nerve at its point of entry into the larynx. The lower laryngeal nerve is less than 3 mm from this ligament generally, runs behind it and must be identified before cutting the ligament. The dense and vascular nature of the Berry's ligament, the multiple branches of RLN that may be present at this level, the presence of nerve curvature at its laryngeal entry point and the close relationship of thyroid tissue to this ligament makes this region the most difficult area of nerve dissection during thyroidectomy.[7,18]

The tracheoesophageal groove is easily usable in locating the left and right RLN because of the deviation of the esophagus to the left and the generally vertical path of the nerve in the tracheoesophageal groove.

The case of right RLN not seen in our series might be a very small nerve or unusual position; the excision of the lesion having been made by strict dissection upon contact. Cases of difficult identification of RLNs as in surgical revisions may benefit from neuromonitoring,[12,19,20] or staining methods.[21] There are limitations to these other means of identification:

- RLN monitoring is essentially a nerve stimulation technique whose major interest is bilateral thyroid or parathyroid surgery and revision surgeries. It is a powerful tool that is not for nerve identification but makes it possible to evaluate the prognosis of its future function by the response to its intraoperative stimulation.[19] Apart from the fact that its impact on the occurrence of definitive laryngeal paralysis is not really proven,[12,20] its use comes up against the problem of the relatively high cost ranging from 15000 to 20000 Euro.[22,23]
- The staining methods (patent blue, isosulfan blue, methylene blue), far from being common methods of detection, occasionally meet the phenomena of perioperative or even anaphylactic allergic reactions.[24]

The nerve was non-recurrent (type II path) on the right in one case of our series. This rare anomaly is related to an abnormal development of the aortic arches and is constantly accompanied by a subclavian retro-oesophageal artery (arteria lusoria) sometimes causing dysphagia. This dysphagia was not reported in our case and did not require exploration in this direction.

The unilateral absence of ITA in 6 cases of our series has not been a trap for the discovery of the RLN in our practice; the discovery of the nerve having been made

by dissecting the presumed area of the artery. Authors recognize that ITA agenesis facilitates the exteriorization of the thyroid lobe and the search for the nerve without risk of traction on the latter[4] but may compromise the vascularization of parathyroid glands in case of reckless dissection.[25]

The surgeon's experience did not have a significant impact on the occurrence of complications in this study ($p = 0.24$). Studies do not agree on this. Some do not find a difference in recurrent morbidity according to the expertise of the surgeon while others show very clearly a lower rate of recurrent paralysis when the intervention is performed by experienced surgeons. For Trésallet et al,[2] what is remarkable in the different studies is the paramount importance of the general experience of the centre where the patients are operated; young employees being able to achieve results close to those of seniors if they follow carefully and rigorously accurate and evaluated operating protocols.

Conclusion

This observational cross-sectional anatomico-surgical study supports the existing data on the relationship between the RLN and the ITA by confirming their variability. Nevertheless, it was marked by the predominance of the RLN truncular arterial situation unlike the literature that most often reports a situation of the nerve under the arterial branches of the ITA. This situation suggests the possibility of anatomical changes related to the usually large thyroid masses in our practice setting. The high rate of nerve discovery and the virtual absence of anatomical nerve damage confirm the prominent place occupied by the visual identification of RLN from ITAs in thyroid surgery. The anatomical integrity of the RLN is not a guarantee of its functional integrity, because of the possibility of transient paralysis, intraoperative monitoring of RLN could help improve the prognosis of future nerve function.

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Conflict of interest: none

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Otosclerosis Revisited

C V Srinivas[1]

ABSTRACT

Introduction:

Otosclerosis usually manifests as a progressive conductive or mixed hearing loss occurring clinically to varying degrees in 0.5% - 1% of the general population. Stapedectomy /stapedotomy is the current treatment of choice for conductive component of Otosclerosis.

Materials and Methods:

Sixty patients attending the department of ENT of a Medical College Hospital in Bangalore between October 2012 and October 2017 were included in the study.

Results:

The incidence of otosclerosis is highest in the 3rd and 4th decade. Bilateral symptoms were present in 25% of the patients and 75% had unilateral symptoms, right side was more common in our study. Tinnitus and vertigo with deafness were seen in 60% and 25 % of the patients respectively.

Ninety percent of the patients presented with moderate to moderately severe hearing loss. Twenty four (40%) out of 60 audiograms studied showed Carhart's notch. Post-operative closure of air-bone gap to within 10dB could be achieved in 65% cases. The p value calculated comparing pre and post op results is <0.0001 and significant.

Vertigo was found to be most common post-operative complication (35%) followed by sensorineural hearing loss (6.6%). Other complications observed during the study include - tympanic membrane tears, foot plate extrusion, lax long process of incus, perilymph leak.

Conclusion:

From the assessment of the postoperative hearing gain and postoperative complications, it can be concluded that small fenestra stapedotomy gives satisfactory post-operative outcome and may be appropriatein the Indian scenario.

Keywords:

Otosclerosis; Stapedotomy

Otosclerosis is one of the commonest non infective causes of acquired deafness in adults'. It is a primary and exclusive disease of otic capsule of human temporal bone. Otosclerosis is characterized by alternate phases of bone resorption and formation. If the location of bony changes produces evident clinical manifestations the term "Clinical Otosclerosis" is used. If bony changes are not translated into clinical manifestations, the term used is "histological Otosclerosis". Antonio Valsalva in 1735 gave the first description of ankylosis of stapes to margins of oval window. Von Troltsch in 1881 coined the term 'Otosclerosis'. Politzer in 1893 first described Otosclerosis as a primary disease of otic capsule. Otosclerosis usually manifests as a progressive conductive or mixed hearing loss occurring clinically to varying degrees in 0.5% - 1% of the general population. Therapeutic options for Otosclerosis include medical, surgical and use of hearing aids, alone or in combination. Stapes surgery is an effective treatment for hearing loss and tinnitus of Otosclerosis and stapedectomy/ stapedotomy is the current treatment of choice for conductive component of Otosclerosis.

The procedure of extracting the stapes for Otosclerosis was first performed by Jack of Boston in 1892 but was beset with obvious difficulties because he lacked proper magnification and antibiotic coverage. In 1956 Dr. John Shea revived the stapedectomy operation for Otosclerosis and replaced the stapes bone with a polyethylene tube prosthesis and vein graft. Stapedotomy is a more precise method of creating a hole in footplate rather than total footplate removal. It gives less post-operative vertigo

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and better high frequency hearing compared to total footplate removal.

The present study is a longitudinal clinical study on Otosclerosis with emphasis on clinical and audiological features, per operative findings, outcome and complications of stapedectomy. Patients with stapedial otosclerosis, above 12 years of age of both gender were included in the study, however patients with pure sensorineural hearing loss were excluded from the study. The objective is to study the demographic and clinical features of Otosclerosis; to analyze the results of audiometry and operative notes of Otosclerosis; to describe the outcome and incidence of complications of stapes surgery in Otosclerosis.

Materials and Methods

The study included 60 patients who were diagnosed to have clinical Stapedial Otosclerosis. They underwent small fenestra stapedectomy in the Department of ENT of a Medical College Hospital in Bangalore between October 2012 and October 2017. Thus totally 60 ears affected by Otosclerosis were studied.

Clinical Evaluation: After recording demographic data, a thorough history was taken and clinical examination performed. The onset, duration, progression of hearing loss was recorded. History of tinnitus elicited. Otoscopic examination and Tuning Fork tests were performed. Tuning fork tests with 256, 512 and 1024 Hz are done. Haematological investigations along with investigation for Cardiovascular and Respiratory System were done. An informed consent was taken explaining all the possible complications associated with the surgery. Patients were kept nil per mouth overnight. A day before thorough shampoo and head bath was advised to all the patients. Premedication was given by Inj Pentazocine 30mg and Promethazine 25mg via intramuscular route.

Technique of Small Fenestra Stapedectomy: Local infiltration of the External Auditory Meatus is done with 2% lignocaine with 1:2,00,000 adrenaline . All the patients are operated upon by the author.

Vascular strip is carefully injected with 2% lignocaine with adrenaline (1:200000). A tympanomeatal flap is raised, the chorda tympani nerve is identified and preserved to gain exposure to the oval window region. Tip of the pyramidal process and the horizontal portion of facial canal over the oval window are visualized. The Stapedial tendon is divided sharply. The stapes superstructure is removed. A small (approximately 0.6mm in diameter) fenestra is made in the posterior half of the footplate using a pick or hand drill. The Teflon piston (0.5 mm diameter) is then inserted through the fenestra to a depth of about 0.25mm in the vestibule. It is then crimped to the long process of Incus. A tissue seal is made around the piston with fat, blood clot or gel foam.

Post-operative Care: Post operatively patients were continued on broad spectrum antibiotics with analgesic, antihistamine and systemic decongestant given to avoid nasal discharge and upper respiratory tract infection. Patients without any complications were discharged on second post-operative day. Patients were advised to avoid sneezing and sudden movement of the head and neck for 48 hours. On discharge, oral form of antibiotic was given with antihistamine for next one week.

Follow up: Patients were advised to attend the outpatient department on sixth post-operative day and ear was examined. Antibiotic continued for 3 weeks. Antihistamine was continued for another two weeks. During the third post-operative visit at 4 weeks, the gel foam, if remaining, was removed and status of tympanic membrane checked. External ear canal and tympanic membrane is especially looked for any granulation tissue formation. Any other complaints if present are tackled accordingly. Patients were advised to come after three months. During this visit status of tympanic membrane is again assessed by otoscopy. Pure tone audiogram is done and the results compared with pre-operative audiogram. Regarding ethical point of view no patients are subjected to any further risk during the study. No further investigations are done. No new methods were tried during this study.

Results

The age of patients varied from 20-50 yrs. Majority of patients were in 30-40 years age group (56.6%). The next common age group is 21-30 years. Age and gender distribution and age of onset of hearing loss is shown in

Table I: Age and gender distribution, age of onset of symptoms

GENDER	NUMBER	PERCENTAGE %
Male	25	42
Female	35	58
AGE OF ONSET	**NUMBER**	**PERCENTAGE %**
< 10	3	5
11-20	12	20
21-30	15	25
31-40	24	40
41-50	6	10

Table II: The side of involvement and incidence of symptoms

SIDE AFFECTED	NUMBER	PERCENTAGE %
Both sides	15	25
Predominantly Right	24	40
Predominantly Left	21	35
SYMPTOMS	**NUMBER**	**PERCENTAGE %**
Deafness	60	100
Deafness+ tinnitus	36	60
Deafness+ vertigo	15	25
Paracusis	9	15

Table I.

Patients below the age of 20 years were diagnosed clinically and classic Carhart's notch.

Twenty five percent patients presented with bilateral symptoms and 75% had unilateral symptoms. Hearing loss was present in all the patients. Other associated symptoms were tinnitus and vertigo, shown in Table II.

Patients gave history of vertigo with deafness were included in the study, however they were operated when they did not have an active episode of vertigo.

Tympanic membrane: Otoscopy of the patients in the present study showed normal appearance in 45 patients(75%), retraction in 9 patients (15%)and myringosclerosis in 6 patients(10%). No middle ear pathology was found in these patients after exploratory tympanotomy.

Approximately 90% of the patients presented with moderate to moderately severe hearing loss. There are no patients with minimal or profound hearing loss. 24 (40%) out of 60 audiograms studied showed Carhart's notch .90% of the patients showed air-bone gap between 31-50dB. The study showed 'As' type of curve in (27) 45% of the patients.

The details of the audiological investigations are shown in Table III.

Patients with mild conductive hearing loss (21-30 dB) also were surgically treated as per Robert Vincet, Causse's Clinic protocol was followed in the current study.

No middle ear pathology found intraoperatively in patients with B type tympanogram.

Length of the piston used in present study: Piston length of 5 mm is used in 60% of cases and 4.5 mm in 20% of cases , 4.75mm in 15% cases, 4.25 mm in 5 % cases.

Complications following surgery: During the post operative period 35% of the patients presented with the complaints of vertigo, which lasted for three to five days and treated conservatively. 6.6% had SNHL postoperatively. (Table IV)

Tympanomeatal tear was found in 15 patients was repaired using tragal perichondrium.

Discussion

In the present study 60 patients underwent small fenestra stapedectomy for Stapedial Otosclerosis, their demographic data, clinical findings, audiological assessment are recorded and analyzed. Complications following small fenestra stapedectomy are also analyzed. Although the sample size was small, the results obtained are compared to similar studies in the literature. The mean age of patients included in the study is 34 years. Mean age of male patients is 36 and female patients is 33years. In the present study more younger female patients are found with Otosclerosis than male patients. In 2005 Quaranta et al in a study of 151 patients with Otosclerosis, found the mean age to be 46 years.[1] The mean age of onset of symptoms in this study is 28 years. In a similar study the mean age of onset in different countries is found to be; 33 in Panama, 29 in Minnesota, 24 in Chile and 23 in Brazil.

In the present study the female preponderance is 1:2 which is similar to other studies by Schmidt in 1933 (72.5%), by Shambaugh in 1952 (68%) and by Cawthorne in 1955 (67%).[2] Comparison of studies for bilateral disease showed a large incidence in the present study (83.7%); in a study by Glasscock et al the incidence was 72%, Ginsberg et al had 80% and in a study by Levy et al it was 66%. The primary symptom in Otosclerosis is gradually progressive hearing loss. The magnitude of hearing loss is directly related to the degree of fixation of stapes footplate and the duration of hearing loss. 90% of the patients presented within 3 yrs of onset of symptoms. The duration of hearing loss was studied by Lippy et al[3] in 1999 compared the trend of disease in the 1960's, 1970's, 1980's and 1990's and found that incidence to decrease from 18.3 years in 1960's to 14.6 years in 1970's, 16.3 years in 1980's and 11.1 years in 1990's; 60% of the patients in this study gave history of Tinnitus.

History of vertigo is elicited in 25% of the patients. Goodhill proposed that tinnitus in Otosclerosis was a class of 'unmasked visceral tinnitus' which could be a feature of any pathology associated with conductive deafness and is due to normally sub audible tympanic and peritympanic vascular and muscular noises that are unmasked by the conductive deficit.[4] A positive history

Table III: Showing pre-op audiological findings and post operative a-b gap

PRE-OP HEARING LOSS	NUMBER	PERCENTAGE %
Minimal (15-25)	0	0
Mild (16-40)	6	10
Moderate (41-55)	21	35
Moderately severe (56-70)	27	45
Severe (71-90)	6	10
Profound (>90)	0	0
PRE-OP A-B GAP	**NUMBER**	**PERCENTAGE %**
0-10	0	0
11-20	0	0
21-30	3	5
31-40	30	50
41-50	24	40
>50	3	5
PRE-OP TYMPANOGRAM-TYPE	**NUMBER**	**PERCENTAGE %**
A	30	50
As	27	45
B	3	5
POST OP ABG (DB)	**NUMBER**	**PERCENTAGE %**
0-5	30	50
06-10	9	15
11-15	15	25
16-20	6	10
>20	0	0

Table IV: Showing incidence of post operative complications

COMPLICATIONS	NUMBER	PERCENTAGE %
Vertigo	21	35
SNHL	4	6.6
Revision piston displacement	2	3.4
Footplate extrusion & replacement	1	1.6
Lax long process of incus	1	1.6
Injury to chorda tympani	0	0
Injury to facial nerve	0	0
Perilymph leak	1	1.6
Tympanic membrane tear	15	25
A/C otitis media	0	0
Labyrinthitis	0	0
Meningitis	0	0

of Paracusis Willisii was found in 15% of patients. Wager in 1939 showed familial incidence in 58% of patients in his study. Cawthorne showed the incidence to be 54.5% and Larsson in 49% of his patients. Worsening of hearing is noted in 60% of his patients by Panama in 1987. Similarly clinical onset of Otosclerosis is reported in 16.6% of the patients of Brazil, 14% of Puerto Rico and 10% of Minnesota patients in his study.

The physical appearance of tympanic membrane is usually normal in most patients with Otosclerosis. In about 10% a positive Schwartz's sign is identifiable. In this study 75% patients had a normal intact tympanic membrane, 15% had mild retraction and 10 % had myringosclerosis. The key objective measurement in Otosclerosis remains the pure tone audiogram. 45% of the patients had moderate to moderately severe hearing loss pre operatively and 90% had a-b gap of 31dB to 50 dB. Air bone gap below 20dB and above 55dB is not seen in the present study. Type A Tympanogram is found in 50% of the patients and As type of Tympanogram is seen in 45% of the patients. As the middle ear aeration is un-affected in Otosclerosis Type A Tympanogram is seen usually and As type of curve is seen in later stages.[5] In the present study all the patients are operated through transcanal approach.

In a study published in 1999 by Lippy et al, a decrease in incidence of obliterative footplate was noted. Smyth and Hazzard (1978) in a study of 655 cases found an incidence of 64% in circumferential type, 28% in biscuit footplates and 8% in Obliterative Otosclerosis.[6] Various types of pistons are preferred by different authors. In the present study Teflon piston of 0.5 mm diameter is used in all the patients. The length of the piston depends on the distance from the incus to the stapes footplate. This

distance together with an extra 0.25mm (extra length is the depth to be inserted into the vestibule) is measured in each case and the length of the piston was cut to size with measuring jig and rod. Most commonly used length was 5mm (60%), followed by 4.5mm (20%), 4.75mm (15%) and 4.25mm (5%). Post-operative Pure Tone Audiogram is taken at 3 months. Post-operative Air Bone Gap (AB gap) recorded in all the patients is analyzed. 65 % of the patients showed AB gap within 10 dB and the rest showed within 20 dB. There are no patients with AB gap more than 20 dB in this study. The mean post-operative AB gap is 9.2 dB in this study. The Pre-Operative and Post-Operative results of closure of a-b gap is statistically significant with p value <0.001. By conventional criteria this difference is considered to be extremely statistically significant. Quaranta et al in 2005 reported 84.8% of small fenestra stapedectomy had a post-operative AB gap within 10 dB and mean post-operative AB gap as 6 dB.

The most common post-operative complication which occurred in our study is post-operative vertigo (35%). Tympanic membrane tear occurred in five cases (25%). During Post –Operative follow up with audiogram, evidence of SNHL found in 6.6 % the present study. Palva et al reported in his study of 456 ears (360 patients) of three drum perforations – one infected and two dry; perilymph fistula in 7 and sensorineural hearing loss in 6.[7] Larsson et al reported delayed facial palsy in 7 out of 706 stapedectomy operations. They proposed a viral origin and suggested prophylactic therapy with acyclovir during the whole perioperative period in all patients with history of HSV reactivation.[8] Hannley et al in 1993 reported a 2.8% rate of sensorineural hearing loss after stapedectomy.[9] Lippy et al in 1999 encountered 2 cases of sensorineural hearing loss and 6 cases of tympanic membrane tear in their study. Surgical approaches in treating Otosclerosis need not be stereotyped. It is possible to use a variety of techniques, depending on the pathologic conditions and anatomic characteristics encountered during stapes surgery.

The major objective is to improve hearing significantly, with or without a hearing aid and to avoid complications. This is a limited study with 60 patients, insufficient to give a significant epidemiological record. The duration of the study and follow up period is also not sufficient to give long term effects of small fenestra Stapedectomy response. Stapes surgery is indicated in a patient with hearing threshold 20dB or worse, a negative Rinne at three consecutive lower frequencies of 256, 512 and 1024 Hz. The speech discrimination if found good is an added benefit of predicting favourable prognosis.[10] Stapes should be firmly fixed and when there is very early partial fixation, stapes surgery is best delayed until fixation is more complete because there is only a little hearing improvement to be gained and much to be lost in case of severe cochlear reaction.[11] A successful stapes surgery not only corrects the entire conductive component of loss but it also removes the variable Carhart's notch with over closure of the pre-operative air-bone gap. Thus stapes surgery can be used for improving the hearing aid usage in presence of stapes fixation and a profound hearing loss, provided there is good speech discrimination.

Conclusion

Present study shows the incidence of Otosclerosis is similar to the literature reviewed world over; this study showed same incidence in both gender and the age group is between 3rd and 4th decades. All patients in our study presented with hearing loss (100% cases). Small fenestra Stapedotomy is an ideal method of surgical intervention in the Indian Scenario as it is devoid of major post-operative complications or vertigo. 5 mm length piston was used in 60% cases with minimal post operative complications. Small fenestra Stapedotomy results showed mean closure of a-b gap to be 10dB in the study which is significant statistically and may be appropriate in the Indian context.

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Case Report

Maxillary Dentigerous Cyst Associated With Supernumerary Tooth

Prashant Nanwani[1]

ABSTRACT

Introduction:

Dentigerous cysts are caused by a developmental abnormality derived from the reduced enamel epithelium of the tooth-forming organ. Dentigerous cyst rarely involve impacted supernumerary tooth in anterior maxilla while commonly involve third molar tooth.

Case Report:

A case of dentigerous cyst in association with supernumerary tooth in a 15-year-old male patient is reported causing right nasal cavity obstruction. The present case report describes the management of a dentigerous cyst by surgical enucleation.

Keywords:

Dentigerous Cyst; Tooth, Supernumerary; Maxilla; Nasal Obstruction

Dentigerous cysts are one of the most prevalent types of odontogenic cysts, mostly associated with an embedded or unerupted tooth. Dentigerous cyst may involve supernumerary teeth, impacted teeth, odontomas and rarely decidual teeth.[1] These are usually associated with mandibular third molar, maxillary permanent canine, mandibular premolars, maxillary third molars in decreasing order. These rarely involves central incisors, supernumerary teeth eg. mesiodens and distomolars.[2]

Stafne et al reported that the incidence of dentigerous cysts associated with supernumerary teeth is only 5.5% most developing around a mesiodens in the anterior maxilla.[3] 'Mesiodens' are the most common supernumerary teeth situated between the maxillary central incisors.0.15% to 3.8% incidence of supernumerary tooth is found in population with 90% to 98% in maxilla, preferably in premaxilla.[4,5] Dentigerous cysts usually found at first to fourth decade of life with slight male predilection.[2]

The reduced epithelium forms bed for the origin of dentigerous cyst because of cystic degeneration of remaining enamel organ which leads to accumulation of fluid by degeneration of epithelial cells.[6] These are usually incidental findings in routine X-rays.

There are various treatment options for dentigerous cyst, ranging from marsupialisation to complete enucleation, including the exodontia of unerupted tooth.[7]

We are presenting a dentigerous cyst in upper maxillary region in a 15-year-old male, associated with a supernumerary tooth; causing right sided nasal obstruction. We shall review the relevant literature.

Case Report

A 15 years old boy reported to the department of ENT & Head & Neck Surgery, with chief complaints of swelling over right cheek since three and half months, right sided nasal obstruction since1 month and pain over swelling since 15 days.(Fig. 1) The boy had history of seizure disorder and was on regular treatment for the same; since 5 months (Tab. Phenytoin 50 mg tds).

Intra-oral examination revealed firm, non-tender swelling over maxillary right gingivolabial sulcus spanning from lateral incisor second premolar.(Fig. 2) The overlying palatal and labial mucosa were normal.

On anterior rhinoscopy, there was bulge over lateral

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Fig.1. Swelling over right cheek

Fig.2. Intra-oral examination showing swelling

wall of right nasal cavity due to swelling over right cheek which was causing right sided nasal obstruction. (Fig. 3)

Fig.3. Showing bulge in right nasal cavity

USG of right cheek swelling showed a well-defined anechoic cystic lesion of size 2.8x2.9 cm seen in the right maxillary region with echogenic component (most probably a tooth), findings suggestive of dentigerous cyst.

CT Scan PNS showed a well-defined lesion of size 2.5x2.8 cm showing fluid attenuation with impacted crown of unerupted tooth seen in the anterior medial aspect of right maxillary sinus abutting right lateral wall of nose and inferior turbinate and causing partial obliteration of right nasal cavity. Features are suggestive of dentigerous cyst in right maxilla.(Fig. 4)

HPE-Gross- showed multiple irregular grayish brown soft tissue measuring 1x1x0.5cm along with tooth. Microscopic-showed cyst lined with stratified squamous epithelium with foci of calcification. Findings consistent with dentigerous cyst.

Discussion

Supernumerary teeth noted in less than 1% of population may cause alteration in neighbouring teeth or disorder in dental eruption. Developmental abnormalities and hyperactivity of the dental plate is the most accepted

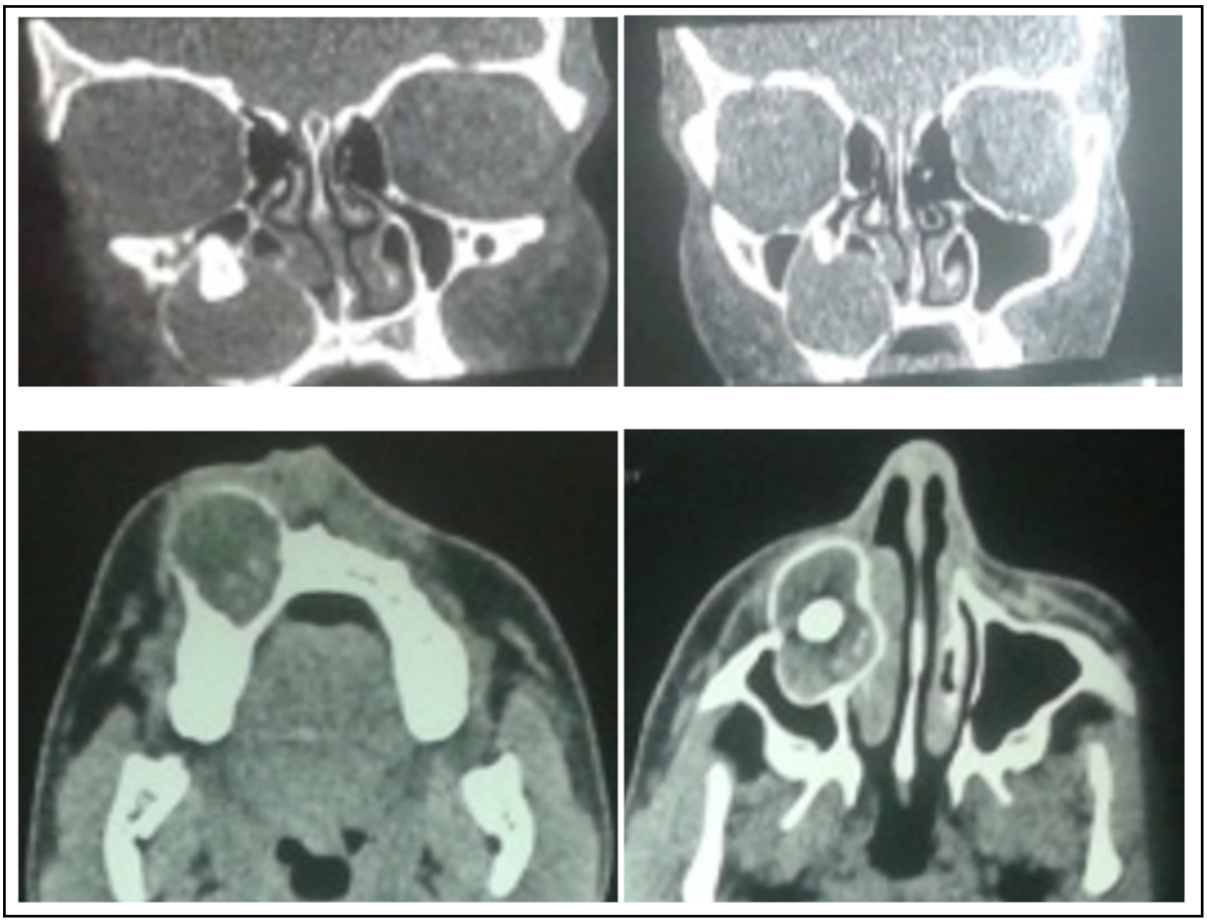

Fig.4. CT scan PNS showing dentigerous cyst with impacted tooth

theory for their formation.[8]

Dentigerous means 'tooth bearing'. Dentigerous cyst is the second most common odontogenic cyst of jaw after radicular cyst.[6,9] Association between dentigerous cyst and supernumerary teeth is an unusual pathology.[7,8,9,10,11] Jiang et al's[10] literature review spanning from 1988 to 2011 discloses the publication of 16 cases of dentigerous cyst associated to supernumerary teeth in the premaxilla.

Zhang et al.[7] in his study found 1% dentigerous cyst were related to impacted supernumerary tooth, 98% were related to molars.

Stafne[3] found that 5.5% of supernumerary teeth developed dentigerous cysts. Hurlen and Humerfelt[12] found a correlation of 7% and Asaumi et al.[13] stated that dentigerous cysts associated to supernumerary teeth account for 11% of the cases.

Theories of Dentigerous cyst formation:

Intra-follicular theory: Fluid accumulates between inner and outer enamel epithelium and resultant cyst formation occurs after crown formation.

Enamel hypoplasia theory: It states that due to degenerative process initially in stellate reticulum stage of tooth development. Enamel hypoplasia is also associated with it.

Main's theory: Accumulation of fluid between reduced enamel epithelium and enamel leads to formation of dentigerous cyst.

Guidelines for diagnosis of dentigerous cyst (Daley and Winsock):[14]

•Greater than 4mm pericoronal radiolucency in

radiology

•Non-keratinising stratified squamous epithelium lining a fibrous tissue

•Cystic space between enamel and overlying tissue demonstrable surgically

Bone cortical affection and neighbouring teeth assessment can be done by maxillary CT scan.[11] The final diagnosis is made according to histological analysis of lesion, where non-keratinised stratified epithelium is found.

Treatment of dentigerous cyst is decided depending on size, location and the probability of disfigurement. If a cyst is very large and in vicinity of vital structure, marsupialisation is done. The cyst should be enucleated along with extraction of involved tooth if cyst is associated with supernumerary or wisdom tooth. If dentigerous cyst left untreated there may be some complications like bone deformity, permanent bone deformation, loss of permanent teeth, squamous cell carcinoma, mural ameloblastoma and mucoepidermoid carcinoma.[15] In our case, enucleation of cyst was done along with removal of impacted supernumerary tooth.

Conclusion

Occurrence of the dual pathology like dentigerous cyst of maxilla and association with supernumerary tooth is quite rare. A CT would be necessary to assess the neighbouring teeth's affectation, quantity of bone involved and extension of the lesion to the surroundings such as nasal cavity, orbit etc. The histopathologic study of the surgically removed piece will determine the confirmed diagnosis.

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Case Report

Fibrolipoma of the Hypopharynx

Kunzang Doma Bhutia,[1] Anandabrata Bose, [1] Anjon Debnath[2]

ABSTRACT

Introduction:
Hypopharyngeal lipomas are rare tumors of head and neck which present with vague symptoms like dysphagia, foreign body sensation in throat, feeling of something coming to the throat or mouth, choking sensations or with symptoms of obstructive sleep apnea. These tumors can cause upper airway obstruction and even asphyxial deaths presenting as medical emergency.

Case report:
We report one such case of a 38 year old female with hypopharyngeal lipoma who had presented to us with symptoms of dysphagia, choking episodes and foreign body sensation in throat.

Discussion:
Laryngoscopic examination in these cases is diagnostic to assess its size and site of attachment. Imaging studies like CT scan or MRI help in diagnosis.

Keywords:
Hypopharyngeal Neoplasms; Lipoma; Dysphagia; Airway Obstruction

Lipomas as such are very common benign tumors of the body but their location in the larynx and the hypopharynx is rare. They represent less than 0.6% of the benign tumors of the larynx and the hypopharynx.[1,2] Because of their relatively rare occurrence and vague symptoms that they cause, it can be confused with other pathologies. Large pharyngeal lipomas even present with respiratory distress due to upper airway obstruction. Here we present a case of such hypopharyngeal mass which had presented to us with symptoms of dysphagia, choking episodes and foreign body sensation in throat.

Case Report

A 38 year old lady, known hypertensive under treatment, non-smoker had presented to us with symptoms of dysphagia, choking episodes and foreign body sensation in throat since 1 month. Her routine head and neck examination was normal except for a mass coming to the mouth on coughing seen on mirror examination. The mass was smooth and floppy which was intermittently obstructing the laryngeal inlet. Its attachment was not seen clearly on indirect laryngoscopy. Videolaryngoscopy revealed a pedunculated mass seen attached to the right posterior pharyngeal wall hanging over the glottis and obstructing the airway intermittently. (Figs. 1 & 2) However, patient did not present with any acute obstructive symptoms like stridor.

Imaging studies with CT NECK revealed a well defined lobulated, fat attenuated lesion measuring 1.5x1.7x2.6 cm in the pharyngeal lumen, attached to the right posterolateral pharyngeal wall with no enhancement on contrast study. Prevertebral, paravertebral soft tissues and adjacent muscles appeared normal.

Patient was then planned for excision of the lesion under general anesthesia. Intubation in this patient was smooth with no difficulty in passing the endotracheal tube.

On examination, the mass was found attached by

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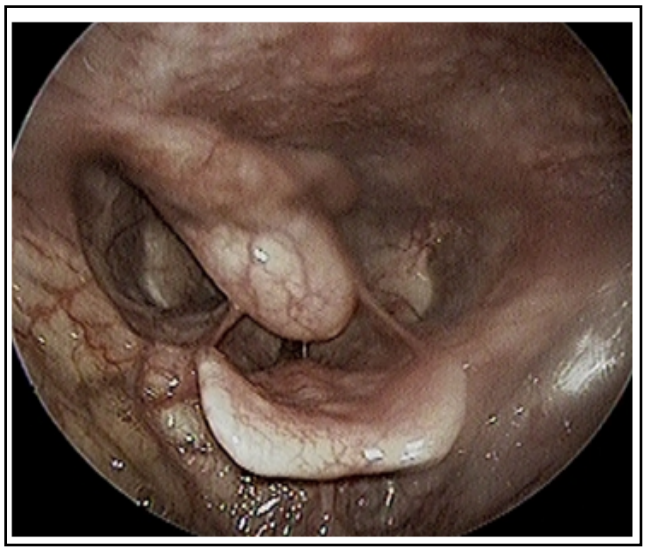

Fig. 1. Pedunculated hypopharyngeal mass

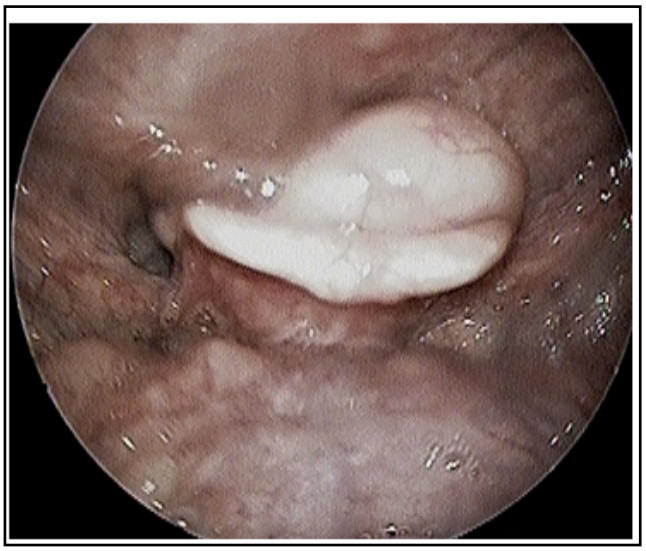

Fig. 2. Mass obstructing the laryngeal inlet

a pedicle to the right posterior pharyngeal wall with easy accessibility transorally.

A Boyle Davis gag was applied and the mass with its attachment was visualized with the help of microscope and removed with scissors and diathermy. (Fig. 3) The pharyngeal excision site was left unsutured and specimen sent for histopathological examination. After surgery, patient had immediate relief in her symptoms and discharged the next day. Endoscopic examination after 1 week revealed a healthy scarred stump at the site of excision. Patient was followed for a period of 2 months with no recurrence and is still on follow-up.

Histologically, the tumor was reported to be a 2.8x 2.5x1.5 cm sized bilobed pedunculated fibrolipoma displaying large islands of adipose tissue, punctuated by bands of fibrocollagenous tissue. The tumor was lined externally by pharyngeal squamous epithelium with no evidence of malignancy. (Fig. 4)

Discussion

Lipomas are mesenchymal tumors derived from mature adipocytes and characterized by their slow rate of growth.[3] Although common in the soft tissues of neck, they are rarely seen in the upper aerodigestive tracts. They may be single or multiple, sessile or pedunculated, and well encapsulated with smooth fleshy consistency.[3] They are reported to occur more often in the elderly.[4]

The etiology of lipomas is unknown; however some authors have suggested that they derive from lipoblasts or by a metaplasia of muscle cells, while others have suggested a possible etiopathological role of familial and endocrine factors or conditions such as trauma, infection, or chronic diseases.[5]

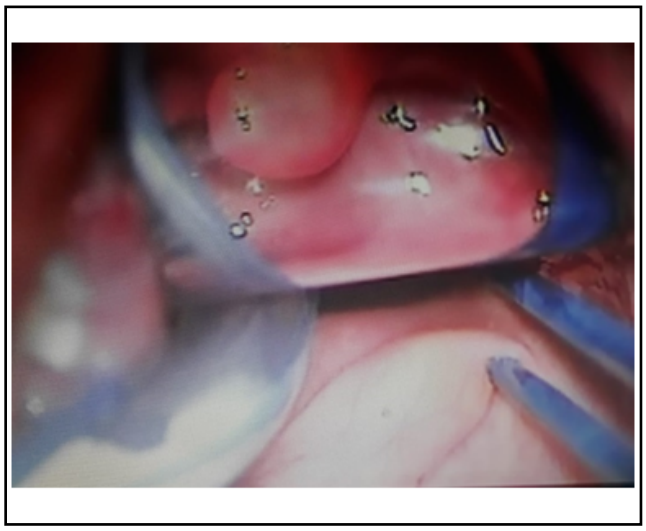

Fig. 3. Intraoperative view of the mass with its attachment

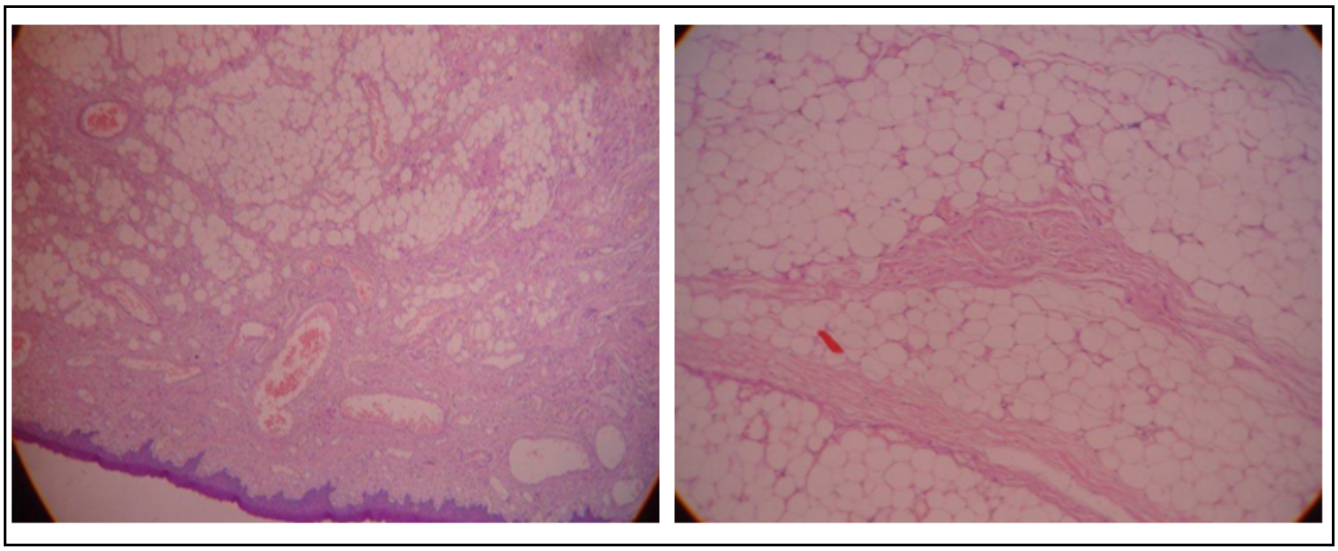

Fig. 4. Microphotograph of the mass (H&E, x10)

Those arising in the hypopharynx can have their attachment to the posterior pharyngeal wall, post cricoid area or the pyriform sinus.

Lipomas are slow growing with patients usually presenting during later stages. They present with symptoms occurring over a course of few months to years which include foreign body sensation in throat or feeling of something coming to the throat or mouth, dysphagia, dyspnea, obstructive sleep apnoea or even asphyxia, depending upon the size and location of the tumor.[5,6] These are generally pedunculated 6 and the tumor may protrude through the mouth on valsalva maneuver or on coughing.[3,5,7]

Literature even reports large lipomas causing asphyxial deaths.[4,8] One of first such case was reported by Penfold in 1952 where a lipoma attached to posterior cricoid area caused asphyxial death in a healthy middle aged women.[4]

Laryngoscopic examination in these patients are diagnostic to assess the size and site of its pedicle attachment. Any obstructive or compressive effects on the laryngeal vestibule and esophagus can also be assessed.

Imaging studies like CT scan or MRI help to know the extent and vascularity of the tumor. On CT scans, lipomas appear as areas of low attenuation (typically approximately -65 to -120 HU) with minimal internal soft tissue component. Areas of calcification may be seen, though are more commonly associated with well differentiated liposarcomas. However, MRI is the modality of choice for imaging lipomas which allows better assessment of atypical features and surrounding anatomy. Lipomas follow subcutaneous fat signals with high signal intensity on T1 and T2 weighted images with no or minimal enhancement on T1 sequences.[9]

Treatment of such lesions include complete excision with histological evaluation and long term follow-up. This is true as long term behavior of these lipomas is still uncertain.[3]

Approach for excision depends upon the location of the tumor and its accessibility. It can be approached via transcervical, peroral or endoscopic technique. Besides diathermy, ablators like harmonic scalpel or coblation can be used in the excision of such lesions.

For huge hypopharyngeal tumors, transoral robotic surgeries can also be considered which provides a 3- dimensional visualization of the resection margin and the dissection plane.[10]

Among the histological variants of lipomas, there are angiolipomas, angiomyolipomas, pleomorphic, benign lipoblastoma, fibrolipoma, chondrolipoma, and spindle cell lipomas based on their stroma.[3]

A qualifying prefix of "fibro" is used for lipomas possessing an unusually prominent connective tissue component.[6]

Histopathological examination of these tumors is necessary to rule out dangerous variants like liposarcomas which bears a resemblance to fat cells. They are differentiated from liposarcomas by the cellular uniformity and lack of lipoblasts and cellular pleomorphism.[3] Immunohistochemistry can be considered for specific diagnosis of the tumor.

Conclusion

Although lipomas of the upper aerodigestive tracts are rare, they must be considered as one of the differential diagnosis of hypopharyngeal masses causing dysphagia. Also large lipomas in this region can be potentially fatal because of the risk of upper airway obstruction. These need to be surgically excised to rule out dangerous variants like liposarcoma, which is a histopathological diagnosis.

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Case Report

Intramuscular Sinusoidal Hemangioma with Masson's Lesion, Masquerading as Parotid Tumor

Tanmoy Deb[1]

ABSTRACT

Introduction:
Sinusoidal hemangioma is a rare variant of cavernous hemangioma, described first by Calonje and Fletcher, more frequently subcutaneous and commonly found on the extremities. Fine needle aspiration cytology report was indeterminate. In such cases preoperative diagnosis is difficult. Slowly growing mass is the usual presenting complaint.

Case Report:
A rare case of intramuscular sinusoidal hemangioma, with typical Masson's lesion masquerading as a parotid tumor, in middle aged woman.

Discussion:
Hemangiomas comprise 7% of all benign tumors and they are benign proliferative vascular tumors characterized by increased endothelial cell turn over. They are usually superficial and easy to diagnose whereas intramuscular hemangiomas (IMH) are uncommon and deep seated and difficult to diagnose. Fifteen percent of the IMHs are found in the head and neck area and the most common muscle affected is the masseter..

Keywords:
Hemangioma; Masseter Muscle; Intravascular Papillary Endothelial Hyperplasia

Pathologists Calonje and Fletcher, were the first to describe sinusoidal hemangioma in 1991. It was considered to be a subset of cavernous hemangioma. It shows a lobular architecture consisting of dilated interconnecting (sinusoidal), thin walled vascular channels lined by a single layer of endothelium.[1] Intramuscular sinusoidal hemangioma (IMH), with typical Masson's lesion is a very rare benign tumour, constituting less than 1.0% of all haemangiomas.[2] We believe it is all the more rare on the face and parotid region.

Case Report

A 40 year old female patient presented to the ear nose and throat (ENT) outpatient department (OPD) of our hospital with complaint of a slowly growing swelling on the left side of her face, which she noticed for the first time about a year back. On palpation the tumor was 3cm x 2.5 cm, ovoid, with smooth surface and firm in consistency, mobile located in the parotid region and very close the angle of the mandible. (Fig.1) The swelling was mildly tender and there was no local rise of temperature, pulsation or bruit. The swelling was not compressible. There was no other palpable swelling in the neck. The facial nerve, along with all other cranial nerves, was normal. The overlying skin was not fixed to the tumour. Her general examination was normal. Her preoperative routine tests like complete blood count, blood sugar, liver function and kidney function test etc were within normal limits. FNAC was done but was inconclusive as it drew a few adipocytes and blood cells. NCCT neck was inconclusive too said it did not look like lipoma. So it was decided that excision biopsy under general anesthesia would be the best way out.

Accordingly she was taken up for surgery under general

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Fig. 1. Clinical picture of the tumor in the parotid region.

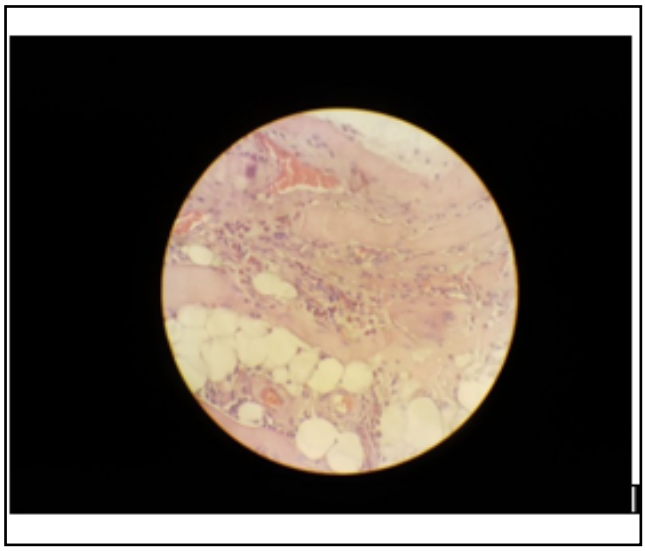

Fig. 2. Photomicrograph showing proliferating endothelial cells and adipocytes (H&E x 100)

anesthesia with the superficial parotidectomy approach through a modified Blair incision. The skin flap was raised but the parotid tissue was found to be normal. The tumor, arising from the masseter muscle, was excised, taking adequate care not to damage the facial nerve, and was sent for histopathological examination (HPE). She was discharged from the hospital on the second post operative day. The sutures were removed on the 7th post operative day. The patient recovered uneventfully and the wound healed. On follow up visit up to post operative 4 months there was no recurrence. The HPE revealed the true nature of the tumor. As is evident in figures 2, 3 and 4 the tumor is a typical intramuscular sinusoidal hemangioma with typical Masson's lesion.

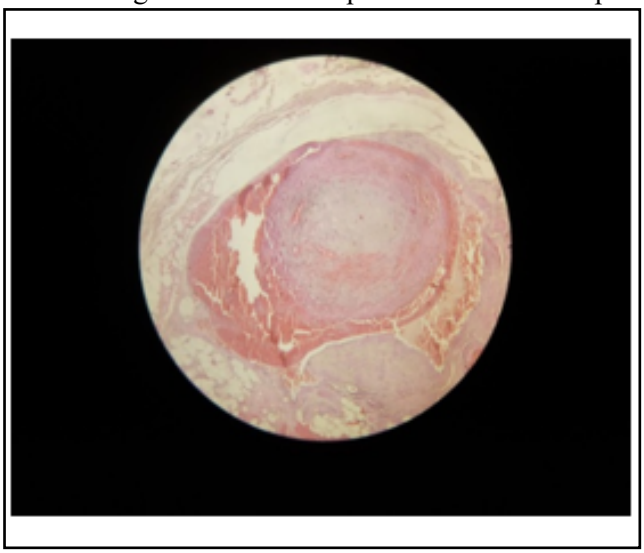

Fig. 3. Photomicrograph showing organizing thrombus within a blood vessel. (H&E x 100)

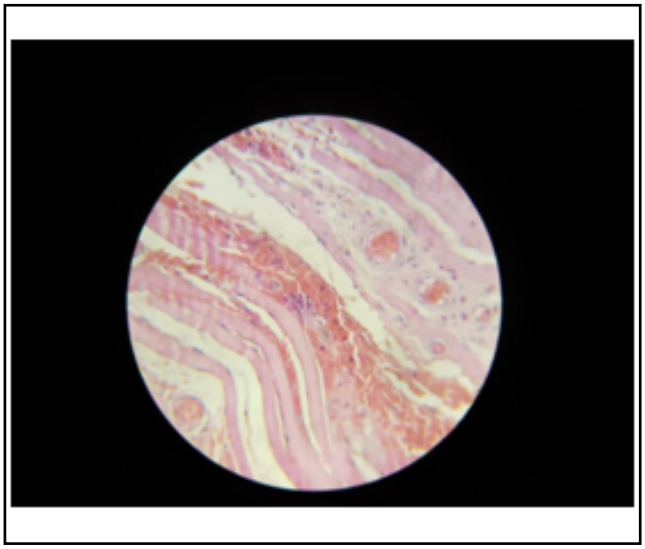

Fig. 4. Photomicrograph showing vascular spaces in between muscle bundles lined by single layer of endothelium. (H&E x100)

Discussion

Differential diagnosis: Intramuscular lipoma has a more indolent course and shows more of fat cells and very less vascular component.[3] IMH can be differentiated from other vascular malformations of skeletal muscles by presence of complete or incomplete lining around the endothelial cells by smooth muscle cells and fibres forming a complete or partially matured wall, which is lacking in other hemangiomas. Angiosarcomas can be identified by presence nuclear and cellular pleomorphism, necrosis and mitotic figures. Intramuscular myxomas and granular cell tumors are characterized by presence of myxomatous and granular cell elements in the tissue. Angiomatosis involving skeletal muscle is another entity which can be very difficult to distinguish, histologically, from intramuscular haemangiomas except from some clinical parameters. Angiomatosis is usually congenital present from birth and involves extensive body areas involving skin muscle and even bone. Intramuscular hemangiomas are benign tumors with a small but definite risk of local recurrence.[4]

Hemangiomas comprise 7% of all benign tumors and they are benign proliferative vascular tumors characterized by increased endothelial cell turnover. They are predominantly superficial and easy to diagnose where as IMH are deep seated and are uncommon and difficult to diagnose.[5] IMH was first reported by Liston in 1843.[6] Intramuscular sinusoidal hemangioma is a distinct type of cavernous hemangioma occurring within the skeletal muscles, constituting less than 1% of all haemangiomas.[7]

Fifteen percent of all IMHs occur in the head and neck area and the most common muscle affected, is the masseter muscle of the face followed by the trapezius muscle in the neck.[8] Although IMH show an equal sex distribution yet masseteric IMH surely has a male predominance.[9] Our case was a female patient having an IMH in the masseter muscle making it all the more rare. The common complaint in IMH is usually an asymptomatic slow growing mass with no aesthetic concerns and no skin discoloration as in superficial haemangiomas.[10] In our case too it was an asymptomatic swelling for the last one year.

Intramuscular sinusoidal hemangioma, first described by Calonje and Fletcher, is characterized by thin walled inter-communicating vascular channels arranged in a sinusoidal pattern.[1] Masson's lesion is a typical finding in IMH and was found in the HPE in our case too as is seen in Fig. 3. Masson's lesion, an intravascular papillary endothelial hyperplasia is a reactive condition representing an exuberant organization and recanalisation of a thrombus, first described Pierre Masson in 1923.[11]

Intramuscular hemangiomas represent a challenge on diagnosis as they exhibit few signs on clinical examination. Often times the extent of the lesion is not clinically apparent on examination. Definitive preoperative diagnosis has been reported in less than 8% of cases.[12] Definitive diagnosis was possible in our case, only after excision and HPE. Preoperative CT scan and FNAC were inconclusive and because of technical constraints sonography couldn't be done.

Conclusion

Intramuscular Sinusoidal hemangioma through rare in the head and neck region should be kept in the differential diagnosis of any tumour in the head and neck region.

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