

The Association of Otolaryngologists of India
West Bengal

p-ISSN: 2395-2393

e-ISSN: 2395-2407

www.bjohns.in

BJOHNs

Bengal Journal of Otolaryngology and Head Neck Surgery

Vol. 31 No. 2 August, 2023



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Bengal Journal of Otolaryngology and Head Neck Surgery

Official Publication of The Association of Otolaryngologists of India, West Bengal

Volume 31 No. 2 - August, 2023

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p-ISSN: 2395-2393

e-ISSN: 2395-2407

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Bengal Journal of Otolaryngology and Head Neck Surgery

(Incorporating and directly descended from State Journal of Otolaryngology and Otolaryngology, Calcutta)

Published by

The Association of Otolaryngologists of India, West Bengal
CMC House, 91B Chittaranjan Avenue,
Kolkata - 700073,
West Bengal,
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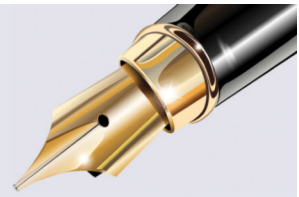
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From the Desk of the Editor



“All work and no play make Jack a dull boy”

In India, rapid urbanization, decrease in playfields in localities, nuclear family with over protective parents, school timings and study pressure and last but not the least, increasing use of smartphones among school going children, all leads to decreasing number of children in playgrounds and as a consequence of lack of exercise, obesity is in a steep rising curve. Due to minimum exposure to external environment there is also a problem in developing immunity among the children and school going kids against common environmental allergens. Childhood and adolescent obesity is at present a growing public health problem in India. In a recent research, prevalence of overweight/obesity among children aged 0–59 months was found to be 2.6%.¹ The prevalence of obesity among 5- to 19-year-old Indian children, ranged between 3.6 and 11.7% and It is predicted that by 2025 there will be 17 million obese children in India.² The prevalence of hypertension, type 2 diabetes, dyslipidemia and non-alcoholic fatty liver disease in children is also increasing with increasing obesity.

Risk of obesity and lack of outdoor exposure in childhood also touches the field of Otorhinolaryngology. Obesity has a direct relation with upper airway obstructive diseases and childhood sleep apnea. There is a definite rise in incidences of recurrent upper airway infections, tonsillitis, chronic cough common viral and bacterial infections of upper airway etc. in last few decades. Lack of outdoor exposure and exercise are definitely major reasons behind this rise.

It is high time to make initiatives to bring the children and school going kids back into the playground to decrease the burden of common ailments related to the field of otolaryngologist. As the under 15 children constitutes almost one third of the patients in ENT OPD and clinics, Otolaryngologists have an important role in this regard. Counseling of the parents by Otolaryngologists in every visit to send their wards to playfields, may serve a crucial role in preventing and controlling many of the ENT diseases among the children.

Sirshak Dutta

Dr. Sirshak Dutta
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Thyroid Dysfunction Following Radiotherapy and Combined Therapy in Non-Thyroid Head and Neck Cancers

<https://doi.org/10.47210/bjohns.2023.v31i2.921>

Rais Ahmad Bhat,¹ Om Prakash,¹ Shabab Lalit Angurana²

ABSTRACT

Introduction

In patients with head and neck cancers thyroid gland bears the brunt in terms of either excision or irradiation resulting in loss of functionality of the gland leading to thyroid dysfunction. The purpose of this study was to evaluate thyroid function following radiotherapy and combined therapy in non-thyroid head and neck cancers.

Materials and Methods

It was a prospective study of 51 patients with head and neck cancers for duration of one year. Thyroid function tests were done before and at the end, 3 months and 6 months following treatment.

Results

Out of 51 patients, 47 (92.15 %) were males and 4 (7.8 %) were females. All the patients received radiation to the neck to a dose of > 50 GY. 36 patients received concurrent chemotherapy and 7 patients underwent surgery. 4 patients were found to have clinical hypothyroidism, 16 patients subclinical hypothyroidism, 1 patient clinical hyperthyroidism and 1 patient subclinical hyperthyroidism. Thus a total of 22 patients developed thyroid dysfunction (P value of 0.001).

Conclusion

Recognizing thyroid dysfunction early and treating it prevents thyroid dysfunction related complications. Hence, thyroid function tests should be done routinely during follow-up in head and neck cancer patients receiving radiotherapy.

Keywords

Head and Neck Cancers; Thyroid Dysfunction; Radiotherapy; Chemotherapy

Thyroid gland is the largest pure endocrine gland in the human body situated in the anterior of neck in front of trachea.¹

Head and neck cancers rank fifth among all malignancy worldwide and commonest malignancy among Indian males. This is probably due to increased use of tobacco and Gutka in various forms.^{1,2} The management of head and neck cancer includes radiotherapy, chemotherapy, surgery and a combination of these. Radiotherapy is one of the most important modalities of treatment of head and neck cancers, besides surgery. Majority of head and neck cancers are locoregionally advanced at the time of diagnosis. Hence radiotherapy treatment field covers the primary site of the tumor and whole neck including the thyroid gland.³

The nonsurgical treatment modality for advanced head and neck cancer is concurrent chemo radiotherapy approach. It improves both loco regional and overall survival for patients with locally advanced head and neck cancer. The chemotherapeutic agent used to improve radiation effect and improve overall survival in head and

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neck cancers are the platinum group of drugs especially cis-platin. Radiation therapy is one of the treatment-modality for patients with head and neck cancer. It is used as curative as well as palliative treatment. It was estimated that over 60% of patients with cancer will have radiotherapy as part of their total course of treatment.⁴

The most common clinical late effect of thyroid gland irradiation in patients exposed to therapeutic doses is hypothyroidism.¹ Though adult thyroid cells are relatively radio-resistant due to their low proliferative index, hypofunction of the thyroid gland is a known side effect of radiotherapy to the head and neck malignancies for more than 40 years.²

Thyroid dysfunction can occur from direct radiation damage to the thyroid gland and or direct functional damage to the hypothalamic-pituitary axis.⁵ The incidence of hypothyroidism is 27%-38% after radiation alone and 40-67% for the combination of radiotherapy and surgery.⁶ Incidence of radiation induced subclinical hypothyroidism is 4%-79%.⁷ A number of studies done as early as 1960s have reported the development of hypothyroidism after radiotherapy for head and neck malignancies with an incidence of 3 to 47%.¹

Hyperthyroidism has also been reported following radiotherapy of patients with head and neck squamous cell cancers with a 17.5% incidence of subclinical hyperthyroidism.⁸

This may occur due to radiation induced thyroiditis. Hyperthyroidism may be classified as overt hyperthyroidism which is defined as high serum T3, T4 and low serum TSH concentrations and subclinical hyperthyroidism which is defined as normal T3, T4 and low serum TSH concentrations.⁹

Hence, the purpose of this study was to evaluate thyroid function following radiotherapy to the neck with or without chemotherapy and or surgery and usefulness of thyroid function tests (TSH, FT3, FT4) in identifying and treating patients with subclinical thyroid dysfunction and to stress upon the necessity of including thyroid function tests as part of follow-up.

Materials and Methods

The present study was a prospective study and was conducted on 51 patients with Non-thyroid Head and Neck Cancers from November 2019 to October 2020. The Study was conducted after taking approval from the Institutional Ethics Committee and in accordance with the principles of Helsinki Declaration 1975. 51 patients with Biopsy/FNAC proven Non-thyroid head and neck cancers in the age group of 23-80 years, both the sexes with pre-treatment normal thyroid function receiving external beam radiotherapy to the neck with or without chemotherapy and or surgery were included in the study. The patients with pre-existing thyroid disease, previous thyroid surgery and history of previous radiotherapy or chemotherapy for Head and Neck malignancy were excluded from the study. Thyroid function tests (TSH, FT3, FT4) were done before treatment in all the cases. The patients were divided into three groups on the basis of the type of treatment. Those receiving Radiotherapy only (n=8), those receiving concomitant Chemotherapy and Radiotherapy (n=36) and those receiving Radiotherapy after Surgery (n=7).

The patients were treated with Cobalt 60 teletherapy machine with conventional fractionation of 1.8-2 GY/Fr/day for 5 days a week for 6-7 weeks. The treatment portals included the primary tumor with margin and the whole neck. The treatment intent was either radical or postoperative adjuvant with or without chemotherapy using weekly Cisplatin at 40 mg/m² of body surface area for six cycles. Thyroid function tests consisting of a baseline serum thyroid stimulating hormone (TSH, Reference range 0.35-5.5mIU/ml), free tri-iodothyronine (FT3, Reference range 2.3-4.2 pg/ml), free thyroxine (FT4, Reference range 0.89-1.76ng/dl) were performed in all patients before and after treatment. Patients were evaluated and followed with blood samples for thyroid function estimation at the end of the treatment and thereafter at 3 months and 6 months following the treatment. Thyroid function tests were done in Biochemistry Laboratory using radioimmunoassay kits and automated analyzer was used to calculate the values. Data was entered in Microsoft Excel spread sheet and analyzed and compared using the statistical package for social sciences (SPSS) software (version 21 for windows).

Results

In our study, 51 patients with non-thyroid head and neck cancers were selected as per the inclusion criteria. Of the 51 patients, 47 (92.15%) were males and 4 (7.8%) were females. The patients were in the age group of 23 to 80 years with mean age among males 57.19 ± 11.94 years and among females mean age was 56.75 ± 12.57 years. The majority of the patients were in the age group of 41 to 60 years.

In the present study the occurrence of thyroid dysfunction was the highest in the age group of 41-60 years (12) followed by 61-80 years (9). This analysis showed that thyroid dysfunction is common in elderly and old age groups as compared to young. Hence age is a significant factor in the development of thyroid dysfunction.

The results of our study suggest that hypothyroidism is strongly associated with non-thyroid head and neck cancer treatment. (Table I).

Table I : Thyroid dysfunction before and after treatment

TREATMENT STATUS	HYPO-THYROIDISM	HYPER-THYROIDISM	NORMAL	TOTAL
Before treatment	0	0	51	51
After treatment	20	2	29	51
p-value	P = 0.001			

Table II : Occurrence of thyroid dysfunction on the basis of treatment modality and radiation dosage

TREATMENT MODALITY	CLINICAL HYPO-THYROIDISM	SUBCLINICAL HYPO-THYROIDISM	CLINICAL HYPER-THYROIDISM	SUBCLINICAL HYPER-THYROIDISM	NORMAL	TOTAL
RT (n=8)	0	5	0	0	3	8
CCRT (n=36)	4	7	1	1	23	36
Surgery with Adjuvant RT (n=7)	0	4	0	0	3	7
Total	4	16	1	1	29	51
P-Value	0.0008					

RT = Radiotherapy, CCRT = Concurrent chemo-radiotherapy

The incidence of thyroid dysfunction in general population is 0.02% with female preponderance. In our study 21 (44.68%) out of 47 male patients and 1 (25%)

out of 4 female patients developed thyroid dysfunction with subclinical hypothyroidism being the most common. The radiation dose in RT group and CCRT group was 70

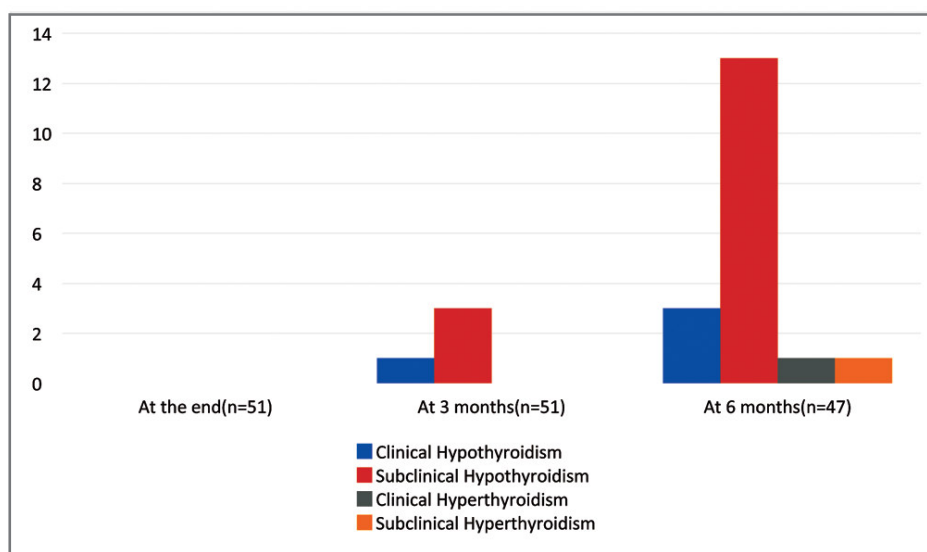


Fig. 1. Time of onset of thyroid dysfunction after completion of treatment.

GY in 35 fractions for 7 weeks, whereas in surgery with postoperative RT group, dose was 54 GY in 27 fractions for 5.2 weeks (Table II).

In our study thyroid dysfunction developed as early as 3 months after the completion of treatment with majority of the patients developing thyroid dysfunction at 6 months after the completion of treatment (Fig. 1).

The mean \pm standard deviation (SD) of TSH, FT3 and FT4 among RT, CCRT and surgery with postoperative radiotherapy groups were analyzed and compared before and at the end, at 3 months and at 6 months after the completion of treatment. The result was statistically highly significant on the basis of mean TSH values among the three groups ($P=0.0001$) (Table III).

Table III : Mean (\pm SD) of thyroid function tests (TSH, FT3, FT4) for operated and non-operated patients

TSH	BEFORE TREATMENT		AT THE END OF TREATMENT		3 MONTHS AFTER COMPLETION OF TREATMENT		6 MONTHS AFTER COMPLETION OF TREATMENT		P VALUE
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	
RT	2.63	0.88	2.42	1.00	2.81	0.85	7.4	4.59	0.0001
CCRT	2.12	1.23	2.1	1.16	2.56	1.96	9.27	19.30	0.0001
Surgery + Adjuvant RT	1.57	0.96	2.33	0.89	13.17	19.38	10.53	11.01	0.0001

Table III (Contd.)

Table III (Contd.) : Mean (\pm SD) of thyroid function tests (TSH, FT3, FT4) for operated and non-operated patients

TSH	BEFORE TREATMENT		AT THE END OF TREATMENT		3 MONTHS AFTER COMPLETION OF TREATMENT		6 MONTHS AFTER COMPLETION OF TREATMENT		P VALUE
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	
FT3									
RT	2.65	0.24	2.63	0.19	2.65	0.29	2.74	0.45	0.89
CCRT	2.62	0.26	2.60	0.24	2.63	0.26	2.63	0.29	0.93
Surgery+ Adjuvant RT	2.55	0.16	2.49	0.15	2.68	0.22	2.60	0.26	0.76
FT4									
RT	1.10	0.19	1.09	0.12	1.08	0.12	1.07	0.13	0.97
CCRT	1.11	0.17	1.11	0.14	1.10	0.16	1.06	0.29	0.89
Surgery+ Adjuvant RT	1.04	0.07	1.05	0.11	1.13	0.08	1.15	0.13	0.02

Table IV : Mean (\pm SD) of thyroid function tests (TSH, FT3, FT4) for operated patients with and without thyroid surgery

TSH	BEFORE TREATMENT		AT THE END OF TREATMENT		3 MONTHS AFTER COMPLETION OF TREATMENT		6 MONTHS AFTER COMPLETION OF TREATMENT		P VALUE
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	
Total laryngectomy with hemithyroidectomy with adjuvant RT	1.51	1.15	3.09	0.37	28.45	22.68	18.11	12.40	0.001

Table IV (Contd.)

Table IV (Contd.) : Mean (\pm SD) of thyroid function tests (TSH, FT3, FT4) for operated patients with and without thyroid surgery

TSH	BEFORE TREATMENT		AT THE END OF TREATMENT		3 MONTHS AFTER COMPLETION OF TREATMENT		6 MONTHS AFTER COMPLETION OF TREATMENT		P VALUE
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	
Surgery other than laryngectomy with adjuvant RT	1.62	0.97	1.77	0.72	1.72	0.63	4.8	6.29	0.45
FT3									
Total laryngectomy with hemithyroidectomy with adjuvant RT	2.59	0.12	2.51	0.18	2.75	0.34	2.71	0.37	0.07
Surgery other than laryngectomy with adjuvant RT	2.50	0.19	2.48	0.15	2.64	0.11	2.50	0.15	0.76
FT4									
Total laryngectomy with hemithyroidectomy with adjuvant RT	1.01	0.02	1.03	0.06	1.08	0.05	1.07	0.10	0.53
Surgery other than laryngectomy with adjuvant RT	1.07	0.09	1.08	0.15	1.16	0.09	1.14	0.16	0.99

Since all the patients received radiotherapy either alone or in combination, so we can conclude that radiotherapy is strongly associated with the development of thyroid dysfunction.

The mean \pm standard deviation (SD) of thyroid function tests in patients who underwent total laryngectomy with hemithyroidectomy with postoperative radiotherapy and in those who underwent surgical procedures other than laryngectomy were analysed and compared. (Table IV).

This suggests that the surgical procedures involving thyroid surgery are significantly related to the development of thyroid dysfunction.

Discussion

The effects of ionizing radiation on thyroid gland in therapeutic neck irradiation (40-70 GY) leads to hypothyroidism. The impact of post irradiation hypothyroidism was first reported in 1929.¹ The first case of hypothyroidism in patients treated for head and neck malignancy was reported in literature in 1961.¹⁰

Documented incidences of primary hypothyroidism after radiotherapy have varied from 3% to 47%. Most of the investigators have reported an incidence of 20% to 30%.¹¹

Our study shows 39.21% incidence of hypothyroidism comparable with literature above. In general, the external irradiation of the normal thyroid may cause dysfunction of the gland within months to years following treatment.

In our study, the incidence of hypothyroidism was 39.21% which is comparable to that of Glatstein et al.¹² who reported 44% incidence of hypothyroidism after irradiation of the neck for Hodgkin's disease.

The study with the longest follow-up of patients was presented by Einhorn J and Wikholm G¹³ who studied 41 patients of carcinoma larynx and hypopharynx treated with radiotherapy (RT) with 10-year follow-up, the incidence of established hypothyroidism was 7.3%.

Alterio et al.¹⁴ stated that among thyroid disorders, primary hypothyroidism seems to be the most frequent late effect with an incidence of 20% to 30%.

Our study found that elderly age group is affected more

compared to young and old age groups, this is supported by the study done by Mercado et al.¹⁵ Our results are also in-agreement with that of Colevas et al.¹⁶ who reported an increased incidence of hypothyroidism in 60 years age group.

In our study, the incidence of hypothyroidism was 40.4% in males and 25% in females suggesting that female gender has no significant impact on the development of post-irradiation hypothyroidism. This is in concordance with other studies like Tell et al.¹⁷ and Bhatia et al.¹⁸ who did not found any significant relationship between gender and development of hypothyroidism post irradiation.

In our study, the incidence of hypothyroidism was 62.5% following radiotherapy alone which is in total agreement with that of Schimpff et al.¹⁹ who reported 64% incidence of hypothyroidism following radiotherapy alone in patients with Hodgkin's disease.

In our study, the incidence of hypothyroidism was 30.55% in patients who received concurrent chemoradiation (CCRT) which is similar to that of Srikantia et al.²⁰ who reported an incidence of 31.25% of hypothyroidism and Turner et al.²¹ who found 36% incidence following chemoradiation. 2 (5.55%) patients in CCRT group developed hyperthyroidism which is comparable to Alterio et al.¹⁴ who found 10.8% incidence of hyperthyroidism following external beam radiotherapy. However, the sample size was small and the follow-up period was comparatively short in our study, this needs a separate study with a large sample size and a longer follow-up in future.

In our study, the incidence of hypothyroidism was 62.5% in patients who received radiotherapy alone as compared to only 30.55% in patients who received concurrent chemo-radiotherapy suggesting that the combination chemotherapy had no significant effect on the thyroid gland in patients with head and neck malignancy, which is in-agreement with that of Posner et al.⁶

Weissler MC and Berry BW,²² Sinard et al.¹⁰ and Tell et al.¹⁷ who found similar results. Aich et al.² on the contrary had a 21% incidence with addition of chemotherapy as compared with 16% with radiotherapy (RT) alone.

In our study, the incidence of hypothyroidism was 57.14% in patients who underwent surgery with adjuvant radiotherapy and the incidence was 100% in patients who underwent total laryngectomy with hemithyroidectomy with adjuvant radiotherapy which is supported by other studies like Posner et al.⁶ who reported 100% incidence and Weissler MC and Berry BW²² who had 92% incidence of hypothyroidism after total laryngectomy with hemithyroidectomy with adjuvant radiotherapy, whereas none of the patients who underwent neck dissection developed thyroid dysfunction which is in agreement with Weissler MC and Berry BW²² who found similar results. Lin et al.²³ on contrary found significantly higher risk of thyroid dysfunction after primary tumor excision with neck dissection (PTE+ND).

We analyzed the occurrence of hypothyroidism, both clinical and subclinical against the radiation dose, it was found to be non-significant. This is supported by Mercado et al.¹⁵ In their study of 155 patients, they observed that the likelihood of developing hypothyroidism could not be predicted according to radiation dosage to the primary site or to the neck. In a study by Koc M and Capoglu I⁸ univariate analysis of various factors failed to identify radiation dose as a relevant risk factor for hypothyroidism.

In our study, the minimum follow-up period was 6 months post irradiation which is lower than other studies. Turner et al.²¹ had a mean follow-up of 21 months. In our study 7.84% developed hypothyroidism at 3 months and 34.04% had hypothyroidism at 6 months of follow-up which is comparable to the study done by Rao D and Shah S¹ who had a minimum follow-up period of 9 months and reported 43% incidence of hypothyroidism.

Our results are comparable with that of Colevas et al.¹⁶ who noted 50% incidence of hypothyroidism in the first year and Aich et al.² who noted hypothyroidism at 6 weeks post radiotherapy (RT) and at 6 months with concomitant chemoradiation (CCRT).

All of the studies stated that recognizing subclinical hypothyroidism at an early stage and treating the same with thyroxine prevents clinical hypothyroidism and also preventing cardiac events by reducing lipid level, as mentioned by Cooper DS.²⁴

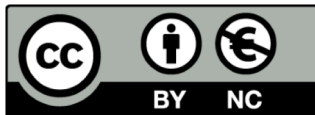
Conclusion

Hypothyroidism (clinical or subclinical) is an under rated, neglected under-recognized morbidity of radiotherapy to neck. The incidence is 39.21%. It can occur as early as 3 months following radiotherapy and increases with time. Addition of thyroid surgery has shown to increase the incidence of hypothyroidism, but addition of concurrent chemotherapy had no significant impact on thyroid function. Hereby, we strongly recommend that thyroid function tests should be done routinely in head and neck cancer patients during follow-ups from as early as 3 months and carried lifelong for long-term survivors.

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Staging of Laryngeal Cancer : Clinicoradiological versus Histopathological Findings using Modified Laryngeal Sectioning

<https://doi.org/10.47210/bjohns.2023.v31i2.767>

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ABSTRACT

Introduction

Laryngeal cancer is commonly encountered in India. Post operative whole organ sectioning of the larynx, although informative, can often be tedious and cumbersome. This study aims to define a modified method of laryngeal sectioning and to assess its level of agreement with pre-operative clinicoradiological findings with regard to T-stage of laryngeal cancer.

Materials and Methods

Prospective study was conducted on 15 patients diagnosed with laryngeal carcinoma, who underwent total laryngectomy with neck dissection. The pre-operative clinicoradiological T-stage, was compared to the post-operative pathological T-stage, obtained after histopathological examination of sections taken from relevant areas of the total laryngectomy specimen using modified laryngeal sectioning.

Results

When compared to the pathological staging obtained after modified laryngeal sectioning, clinical T-staging over-staged the tumour in 3 cases and under-staged the tumour in 2 cases, and was similar in the remaining 10 cases. The level of agreement in determining the T-stage was 'fair'.

Conclusion

The T-stages determined by pre-operative clinicoradiological findings and post-operative histopathological findings after modified laryngeal sectioning, were similar in two-third cases. While whole organ laryngeal sectioning remains the gold standard, it is often a costly and cumbersome process. We propose the use of representative tissue samples from the areas of interest for histopathological examination, obtained by sectioning the larynx at relevant points only, as it saves time and is less resource intensive.

Keywords

Laryngeal Cancer; Clinical Staging; Radiological Staging; Pathological Staging; T-stage; Modified Laryngeal Sectioning; Whole Organ Section

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The larynx is one of the most important organs in the upper aerodigestive tract. It performs crucial functions of airway protection and respiration, serves as the voice box, and assists with swallowing. Cancer of the larynx is a commonly encountered entity in India. Laryngeal carcinoma is the seventh and ninth most common cause of cancer in males in India and Asia respectively.¹

A good preoperative assessment and proper

clinicoradiological staging, helps in formulating the relevant management plan. Staging also reflects on the eventual outcome of laryngeal carcinoma. Imprecise tumour staging from pretreatment imaging could possibly preclude organ preservation in many patients. Further, penetration of the laryngeal cartilage and/or extralaryngeal tumour spread is associated with a lower response rate to radiation therapy and a higher risk of tumour recurrence.^{2,3} These facts illustrate the importance of accurate preoperative evaluation in patients of laryngeal carcinoma.

Whole organ sections of the larynx have been used since several years to increase our knowledge of the histopathological and biological behaviour of laryngeal carcinoma. It is especially useful to understand the spread of laryngeal carcinoma through tissue planes. The first serial laryngeal sections were done by LeRoux-Robert in 1936 and were used to examine laryngeal carcinoma after autopsy.⁴ Kirchner published an article highlighting the contributions of whole organ sections of the larynx to the treatment of laryngeal cancer. He concluded that whole organ serial sections of larynx have provided graphic evidence of the patterns of cancer spreads from one part of the larynx and hypopharynx to the other, and have demonstrated the fibroelastic ligaments and membranes which form the boundaries of intralaryngeal compartments within which cancer is confined in its early stages, and thereby added support to the concept of partial laryngectomy for selected lesions.⁵

Whole organ sections of laryngectomy specimens have undoubtedly facilitated better interpretation of preoperative imaging, while providing additional help with staging of laryngeal cancers. However, the process of whole organ sectioning of the human larynx is a cumbersome one, involving serial sections which are 1-2 mm thick, either in the coronal or the axial plane. These sections have to traverse through varying levels of tissue density, ranging from soft tissue, ligaments, muscles to relatively harder cartilage and bone. Further, problems with grossing and tissue processing of whole organ sections make it difficult to quickly analyse them. We therefore suggest a modification, where tissue specimen is collected by sectioning at the relevant points of interest,

with respect to the staging of laryngeal cancer. These points of interest are accessed by laryngeal sectioning done at specific levels, instead of taking 1-2 mm cuts of the whole organ laryngeal specimen. The T-stage determined by the histopathological examination of specimen obtained after modified laryngeal sectioning was compared to the T-stage determined pre-operatively by clinicoradiological examination.

The aim of this study was to define a modified method of laryngeal sectioning and to assess its level of agreement with pre-operative clinicoradiological findings with regard to T-stage of laryngeal cancer. The reasons for incompatibility between the two were listed.

Materials and Methods

This prospective observational study was conducted at the Departments of Otorhinolaryngology and Pathology, at a tertiary care hospital in West Bengal, between February 2020 to July 2021. 15 biopsy proven laryngeal cancer patients, with advanced and extensive disease (T3 and T4), previously unoperated, and now warranting and consenting for total laryngectomy, were included. Patients with T1 or T2 laryngeal cancer, who did not have a need for total laryngectomy, and for whom radiation and/or chemotherapy, or other less radical surgery would suffice, were excluded. Patients who had been operated previously or had received radiation in the past were also excluded.

Patients coming to OPD with laryngeal carcinoma were assessed clinically. The patients underwent detailed clinical examination, fiberoptic laryngoscopy (FOL), contrast enhanced CT base of skull to clavicle with special emphasis on the larynx and neck nodes. After the relevant work-up, clinical staging was done by amalgamating the clinical findings with the radiological reports.

The patients with T3 and T4a stage, and qualifying the inclusion criteria, underwent total laryngectomy and neck dissection. The total laryngectomy specimen was stored in formalin and transported to the Pathology Department. The laryngectomy specimen was sliced open from its posterior aspect from top to bottom to be able to visualize the inner structures.

Two windows were made in the thyroid cartilage as shown in Fig.1. The first window was created in the midline and another window was created laterally on the same side as the lesion, as observed grossly and on corroboration with radiological imaging. The specimen spanning the entire thyroid lamina was thus collected and then sectioned in a coronal plane so to get clear sections from the both the inner and outer cortex of the thyroid cartilage. The exact site of these windows can vary from case to case. The anterior midline window can be created at the level of the cancerous growth, once it has been properly visualized and the lateral window can be created ipsilateral to the side of involvement of the larynx. Making a window in the midline of the thyroid cartilage is especially important, since the weak spot of the laryngeal framework is the anterior midline, with respect to early cartilage invasion of the tumour and its exo-laryngeal spread. The creation of the two thyroid windows aid in obtaining specimens of the thyroid cartilage, which are then analysed using thin coronal sections for determining involvement of inner and outer cortex of thyroid, which have a bearing on the staging.

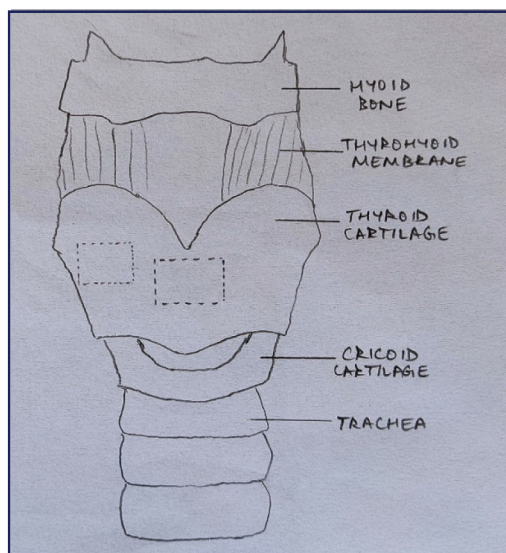


Fig. 1. Two windows being created in the thyroid cartilage. First window is located in the anterior midline grossly corresponding to the level of the cancerous lesion, and the second window is created laterally on the involved side of the larynx.

Instead of serial whole organ sectioning of the larynx at 1-2 mm thickness, representative tissue specimens were collected from the relevant sites which impact the staging of laryngeal cancer, after accessing them with the aid of the three planes through which transverse whole organ sectioning was done as showed in Fig.2.

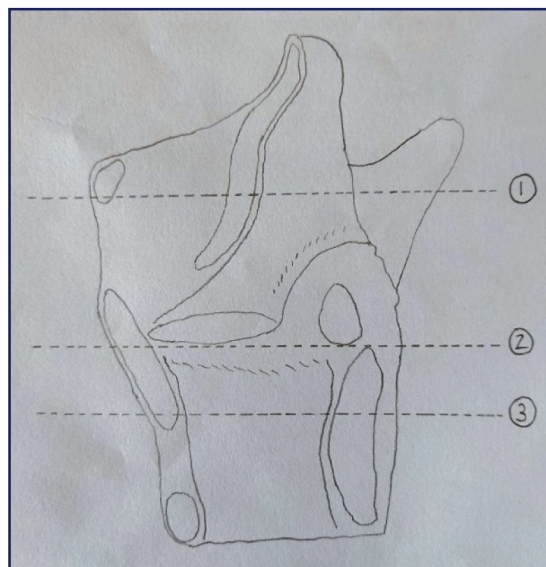


Fig. 2. Three planes through which transverse whole organ sections are made.

The first whole organ section was made at the horizontal plane passing just inferior to the hyoid bone and intersecting the epiglottis. The second whole organ section was made in a transverse plane at the level of the anterior commissure, inferior to the thyro-epiglottic ligament, and the third whole organ section was done at the horizontal plane passing 2 mm inferior to the glottis, ie, 12 mm below the inferior surface of true vocal cord. The whole organ sectioning allowed us access to the areas of interest, thereby enabling better tissue sectioning from these areas. Further sections were taken from the relevant areas as per need of the specific case.

After taking the first and second whole organ sections, the entire pre-epiglottic space was exposed as shown in Fig. 3. Adequate tissue sectioning was then done from the pre-epiglottic space, with the aid of 2 mm axial sections spanning from the first whole organ section and extending upto the second whole organ section. This

allowed us to obtain representative tissue specimen from the entire pre-epiglottic space.

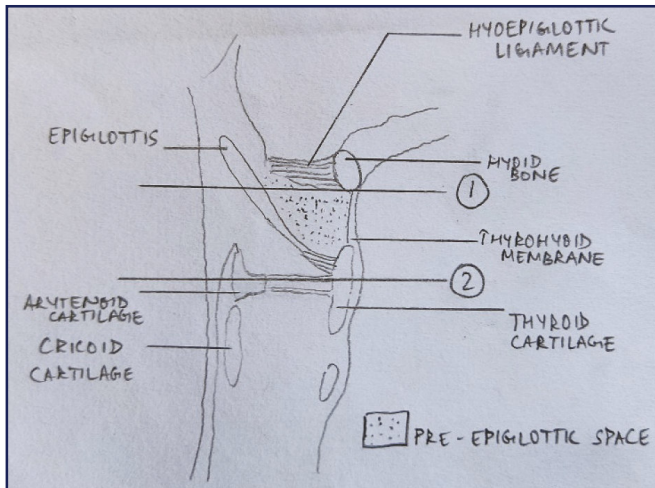


Fig. 3. Pre-epiglottic space exposed after giving first and second transverse whole organ sections.

The second section allowed us to access to the paraglottic space at the level of the glottis. The third whole organ section also allowed access to the paraglottic space, in addition to the post-cricoid area and cricoid cartilage. After having sliced open the whole organ laryngeal specimen from top to bottom in its posterior aspect, and with the aid of aforementioned three transverse whole organ sections, we obtain easy access to the paraglottic space on both sides. The paraglottic space is laterally bounded by the thyroid cartilage, through which representative specimens were already collected. Serial 2 mm thick sectioning is done between the second and third transverse whole organ sections in between the two thyroid laminae, which enables histopathological evaluation of the paraglottic space, post-cricoid area and the cricoid cartilage. Involvement of all these structures have repercussions on the T-stage.

Slicing open the whole organ laryngeal specimen posteriorly, and the subsequent transverse whole organ sections, enabled easy access to the areas of interest that have relevance in determination of T-stage. Further, 2 mm thick sections made between the transverse whole organ sections need not span the entire transverse length of the organ and can be made separately for the right

and left side. This helps in obtaining postage-stamp sized tissue specimens which are easy to handle and study, in stark contrast with the much larger whole organ transverse sections.

Sections were then collected from the thyroid gland, and inferiorly from the trachea. Adequate tissue sectioning was done from the growth proper, after measuring and mapping out its extension. Level 2-4 lymph nodes were analysed histopathologically.

Sections were thus collected from the following sites- pre-epiglottic space, paraglottic space, postcricoid area, inner and outer cortex of thyroid, cricoid cartilage, supraglottis, glottis, subglottis, the growth proper, trachea, cervical soft tissue, strap muscles, thyroid and lymph nodes.

The grossing was done, and the specimens were properly labeled and stored in tissue cassettes, before being processed. The histopathological examination was done by a single senior pathologist. The clinical staging was compared with the pathological staging and discordance, if any, was noted.

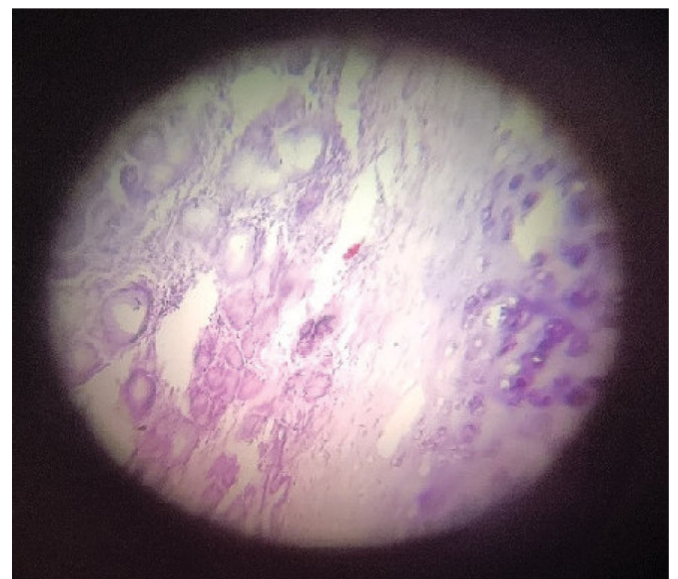


Fig. 4. Histopathological section through the outer cortex of the thyroid cartilage. The section shows hyaline cartilage and benign mucous glands. The cartilage is found to be free from carcinoma. (H&E, 100X)

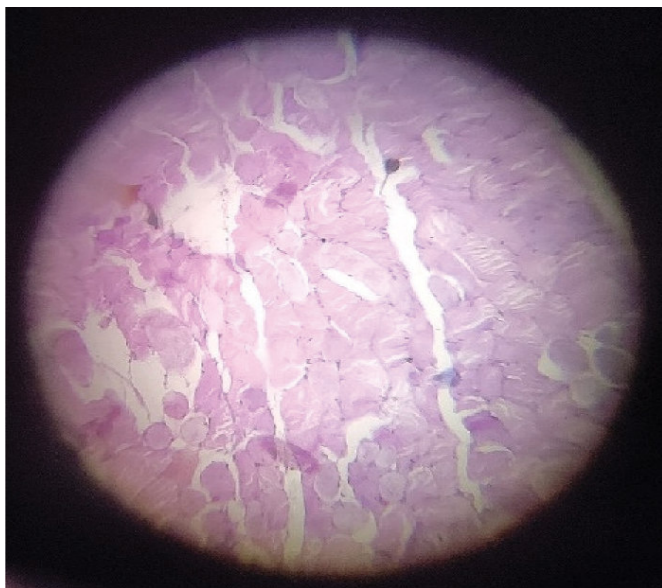


Fig. 5. Histopathological section showing striated muscle fibres of the strap muscles, which are free from the carcinoma. (H&E, 100X)

Results

Patients aged from 52 to 69 years (mean, 61 years). There were fourteen (93.3%) male patients and one (6.7%) female patient. The site of primary malignancy was the glottis in 10 out of 15 patients. 4 patients had a supraglottic carcinoma while 1 patient had a subglottic malignancy. All fifteen patients had squamous cell carcinoma larynx, with varying differentiation.

Compared to the pathological T-stage, clinical T-staging over-staged the tumour in 3 cases and under-staged the tumour in 2 cases, and was found to be similar in the remaining 10 cases. Kappa weighted statistic was used to find out the agreement between the clinical and pathological T-stage, and it showed 'fair agreement' between the two.

Discussion

Between 1964 and 1979, the clinical staging was found to be inaccurate in 40 % of the laryngeal specimens studied by whole organ section.⁶ The inaccuracy was nearly always in the form of underestimation, commonly

due to invasion of the laryngeal framework or because of undetected spread of the cancer into the pre-epiglottic space. Since then, the whole organ sectioning has come a long way and in its current state, is being extensively used for staging and understanding tumour biology and patterns of spread. Kiminori Sato in his chapter on whole organ serial sections of the adult human larynx has graphically depicted the various sites through schematic diagrams and histopathological slides.⁷ It provides a great understanding of the anatomical relations and possible routes of cancer spread.

The whole organ sectioning of larynx, albeit useful for studying the laryngeal cancer spread, can be a tedious and cumbersome process. Even though the value of serial sectioning of the larynx is generally recognized, the process remains laborious and resource intensive, and requires a financial investment and time commitment. In the present study, we have taken tissue specimens from the anatomical sites and areas where the laryngeal cancer is likely to spread, and which have a bearing on the staging of laryngeal carcinoma. These tissues have been accessed through three transverse whole organ sections done at the horizontal levels passing through the plane inferior to hyoid bone, through the anterior commissure and through a horizontal plane passing 2 mm below the glottis. These sections make the areas of interest more accessible, thereby enabling direct tissue sectioning from there. The whole organ sections through the larynx are large and require special processing and larger slides to enable studying them in their entirety. Instead, we propose using representative samples from areas of interest, the access to which is enabled through the aforementioned whole organ sections. The representative tissue thus collected is from a small area of interest and can be easily mounted on a slide and is roughly the size of a postage stamp, thereby rendering it easier to handle and study under the microscope. This method circumvents the complications and tediousness of whole organ sectioning, while retaining the benefit of histopathological examination to appreciate tumour involvement across tissue planes.

In addition to the transverse whole organ sections, we propose making square windows in the thyroid

Table I: Comparison of clinicoradiological and histopathological T-stage

		CLINICORADIOLOGICAL STAGING : T				TOTAL	KAPPA WEIGHTED STATISTIC	INTER- PRETATION
		T1	T2	T3	T4A		Ê W	
HISTOPATHOLOGICAL STAGING AFTER MODIFIED LARYNGEAL SECTIONING : T	T1	0(0)	0(0)	0(0)	0(0)	0(0)	0.400	Fair agreement
	T2	0(0)	0(0)	2(18.18)	0(0)	2(13.33)		
	T3	0(0)	0(0)	7(63.64)	1(25)	8(53.33)		
	T4a	0(0)	0(0)	2(18.18)	3(75)	5(33.34)		
Total		0(0)	0(0)	11(100)	4(100)	15(100)		

Table II: Discordance in T-Stage: Reasons for overstaging and understaging

PRIMARY SITE	cT	pT	REASON FOR OVERSTAGING
Glottic	T3	T2	Paraglottic space was thought to be involved on radiology, but was found not to be involved on histopathology
Supraglottic	T3	T2	Pre-epiglottic tissue was involved on radiology, but spared on histopathology
Glottic	T4a	T3	Outer cortex of thyroid cartilage invaded by tumour on radiology, but found to be spared on pathological analysis

PRIMARY SITE	cT	pT	REASON FOR UNDERSTAGING
Supraglottic	T3	T4a	Outer cortex of thyroid cartilage spared by the tumour on radiology, but found to be involved on pathology
Glottic	T3	T4a	

cartilage. The first window is made in the midline, grossly corresponding to the level of the cancerous growth. The second window is made laterally, ipsilateral to the site of the cancerous involvement. The thyroid cartilage removed through these windows can then be used for coronal sectioning so as to enable us to pathologically assess the involvement of both inner and outer cortices of thyroid cartilage. The midline window is extremely important. It is known that the weakest point of the laryngeal structure is the midline because of the absence of perichondrial tissue at this site, thereby rendering it susceptible to invasion of cartilage by the cancer.⁸

We have compared the T-stage obtained by histopathological examination following modified laryngeal sectioning to the clinicoradiological T-stage and found the T-stage to be similar in 66.67% cases. While whole organ laryngeal sectioning remains the gold standard, with the advent of better imaging techniques, the accuracy of clinicoradiological staging and its ability to ascertain pathways of tumour spread has been on the rise. The accuracy of pre-operative T-staging of laryngeal cancers, as ascertained by various studies by comparing it with histopathological examination following conventional whole organ sectioning is given in Table III.

**Table III : Comparison of accuracy of pre-operative T-staging –
Clinicoradiological vs Histopathological examination following conventional whole organ sectioning**

STUDY	YEAR	NUMBER OF CASES	ACCURACY OF CT SCAN IN PREDICTING T-STAGE
Agada et al ⁹	2004	38	45%
Wolny et al ¹⁰	2006	100	62%
Allegra et al ¹¹	2014	20	70%
Ryu et al ¹²	2014	94	78%
Atlanođlu et al ¹³	2016	28	82.1%
Èelakovský et al ¹⁴	2017	124	87.9%
Jaipuria et al ¹⁵	2018	23	82.6%
El-Sharkawy et al ¹⁶	2019	30	76.6%
Contrera et al ¹⁷	2020	265	82%

In our study, of the 5 cases where there was an inaccuracy in the T-stage, 3 (60%) cases were due to incorrect prediction of cartilage involvement. Similar inaccuracies in evaluating cartilage involvement by tumours have been reported from other studies. The role of computed tomography in detection of cartilage involvement in early glottic tumours was studied by Hartl et al.¹⁸ The authors concluded that CT imaging was

unable to evaluate focally invaded lesions in the inner cortex of the thyroid cartilage. In a study by Jaipuria et al¹⁵ aimed at assessing the accuracy of computed tomography to predict T-stage in laryngeal cancer, CT imaging identified 13 (76.5%) of 17 cases of histopathologically confirmed thyroid cartilage destruction. The most common cause of over staging identified by Agada et al⁹ was arytenoid cartilage sclerosis,

while the causes of under staging included failure to detect thyroid cartilage invasion in one case, which was similar as in our study.

Destruction of the cartilage can often be identified through CT findings such as erosion, lysis, and transmural exo-laryngeal spread. However, irregular ossification of the thyroid cartilage along with the cartilage reaction occurring due to both, invasion by the tumour, as well as proximity to the tumour, perhaps explains the reason as to why CT is often unable to correctly predict cartilage involvement by the tumour.

In our study, we found the pre-epiglottic space to be involved in a third of the cases, while the paraglottic space was involved in 80% cases. Among the cartilages, the involvement of arytenoid, inner and outer cortex of thyroid was 73.34%, 53.34% and 33.34% respectively.

Interestingly, we found the thyroid gland to be histopathologically uninvolved in all the cases in the present study. This leads us to question whether ipsilateral hemithyroidectomy or total thyroidectomy is indeed required in all cases of patients with laryngeal cancer undergoing total laryngectomy. Thyroidectomy exposes the patient to a risk of hypothyroidism and hypoparathyroidism and may not always be indicated in patients with laryngeal cancer. Baghel et al studied the need for thyroid excision along with laryngectomy in carcinoma larynx, and concluded that the invasion of thyroid gland by laryngeal cancer is uncommon, and hence advocated total thyroidectomy to be done along with total laryngectomy in cases which had gross clinical, radiological or intraoperative thyroid gland involvement, subglottic extension and thyroid cartilage invasion.¹⁹ Ceylan et al.²⁰ in their study also concluded that there may not be a need to perform thyroidectomy in all total laryngectomy cases and recommended thyroidectomy to be done in laryngeal carcinoma cases with subglottic extension and advanced hypopharyngeal tumours. There is, however, no doubt that lesions involving the glottic larynx with significant subglottic extension mandate an ipsilateral thyroid lobectomy be done, to facilitate ipsilateral tracheo-oesophageal lymph node clearance.

While whole organ sections have been the

conventionally accepted gold standard for histopathological analysis and have contributed extensively to understanding pathways of tumour spread, they are laborious, costly and yield unwieldy tissue samples which require bigger slides and more time to analyse and interpret. Hence, we propose a modified method of laryngeal sectioning which involves opening up the laryngeal specimen posteriorly, making two windows through the thyroid cartilage at designated spots, and three transverse whole organ sections at specific locations. Subsequent 2 mm cuts can be given akin to whole organ laryngeal sectioning, but these are done for a limited anatomical areas which have a bearing on the T-stage, instead of making several sections through the entire laryngeal specimen. Further, opening up of the larynx allows separate sections to be made for the right and left sides. This facilitates the availability of tissue samples which are smaller and hence easier to handle and analyse.

Conclusion

Conventional whole organ sectioning of the larynx can be a cumbersome and tedious task. We propose the use of modified laryngeal sectioning to obtain representative tissue samples from the areas of interest for histopathological examination, as it is less resource intensive and saves time.

In our index study comparing the T-stages obtained through clinicoradiological examination and histopathological examination using modified laryngeal sectioning, we found 'fair' agreement between the two. A third of the patients were either upstaged or downstaged after histopathological examination of samples obtained through modified laryngeal sectioning.

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Efficacy of Functional Endoscopic Sinus Surgery and Impact of Chronic Lung Disease on its outcome in Patients of Chronic Rhinosinusitis

<https://doi.org/10.47210/bjohns.2023.v31i2.984>

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ABSTRACT

Introduction

Chronic rhinosinusitis (CRS) is a common health condition affecting a significant proportion of population which results in considerable morbidity and deterioration in quality of life. Functional Endoscopic Sinus Surgery (FESS) has gained acceptance throughout the world as a procedure believed to improve the symptoms of chronic rhinosinusitis and consequently the general wellbeing of patients suffering from the condition. Patients with CRS are also known to have comorbidities. Chronic lung disease (CLD) i.e. bronchial asthma, COPD and chronic bronchitis are commonly associated with CRS. In view of the above, this study was carried out to determine the prevalence and severity of various symptom manifestations of chronic rhinosinusitis as well as to compare the symptomatic relief of the patients following surgery by regular follow ups and by using grading systems. This study also evaluated the impact of Chronic Lung Disease (CLD) on the outcome and complications of FESS.

Materials and Methods

This prospective longitudinal cohort study was carried out for 18 months' duration with 50 patients amongst the patients attending the OPD of Otorhinolaryngology with chronic Rhinosinusitis following inclusion and exclusion criteria. A detailed history including associated CLD and other co-morbidities were documented. All the patients underwent pre-operative clinical, radiological and endoscopic evaluation followed by FESS. Post-operative follow up was done at 1 week, 2 weeks, 4 weeks, 8 weeks, 3 months, 6 months, 9 months and 1 year intervals for one year and assessment was done in respect to improvement of symptoms using grading scale where success is meant by complete resolution of symptoms or improvement of symptoms (score +1) and cases with no change of symptoms (score 0) or deterioration of symptoms (score -1) within 1 year of follow-up are said to be failures. Rates of complications were also assessed. Results were analyzed using SPSS software.

Results

The mean age of this study population was 35.60 years with M: F ratio 1.27:1. Majority presented with symptoms of nasal obstruction and nasal discharge. FESS was found to be highly effective in relieving all symptoms- 88.89% for Nasal obstruction, 79.07% for Rhinorrhoea, 80.65% for Headache, 80% for Epistaxis, 75% for Facial pain/ pressure, except for smell dysfunction where it was found to be 53.57%. Among those 21 cases of OM unit patterns 13 (61.9%) were successful after FESS. In case of sporadic form 9 (69.2%), diffuse polyp form 6 (60%), infundibular form 1 (33.3%) and spheno-ethmoidal form 2 (66.7%) were successful. The success rate among CLD patients was 66.6% and those who had no co-morbidities was 65.6%. Similarly, the complication rate in CLD patients was 33.34% where in patients with no co-morbidities it was 31.25%.

Conclusion

The leading complaints within the symptom profile of patients with CRS are nasal obstruction with nasal discharge. FESS is highly effective treatment to relieve all major symptoms of CRS except smell dysfunction. This study also concludes that chronic lung disease has got no influence in the outcome and complications of FESS.

Keywords

Functional Endoscopic Sinus Surgery; Rhinosinusitis; Chronic Lung Disease

Chronic rhinosinusitis (CRS) is a common health condition affecting a significant proportion of population.¹ It is defined by its subjective signs- i.e. intensity and duration of its characteristic symptoms: postnasal drip, nasal obstruction and discharge, facial pressure or pain, headache, cough and olfactory dysfunction lasting longer than 12 weeks. Chronic rhinosinusitis results in considerable morbidity and deterioration in quality of life caused by the above symptoms.

Severity of objective findings used for diagnosis and staging of CRS (x-ray, CT scan of nose and PNS, bacteriology) do not correlate with the subjective symptom scores, but some of the objective signs have been reported to be valuable predictors of poor long term outcomes following conservative or surgical treatment.²

Treatment of CRS can be medical or surgical. After the failure of conservative treatment, functional endoscopic sinus surgery is the preferred treatment.^{3,4} Over the last few decades, Functional Endoscopic Sinus Surgery (FESS) has gained acceptance throughout the world as a procedure believed to improve the symptoms of chronic rhinosinusitis and consequently the general wellbeing of patients suffering from the condition. It is based on the hypothesis that diseased sinonasal mucosa can get reverted if ventilation and drainage are improved, thus restoring mucociliary clearance.^{5,6} Endoscopic sinus surgery (ESS), like all minimally invasive sinus surgery, is designed to combine an excellent outcome with minimal patient discomfort.

Initially thought to be highly effective in management of chronic rhinosinusitis, the relative effectiveness of endoscopic sinus surgery has recently been questioned. Some researchers have cited recurrence rates and incomplete symptoms resolution even after ESS. The varied aetiologies of chronic rhinosinusitis especially the allergic and fungal causes have doubted the impact of ESS in chronic rhinosinusitis. The relationship among FESS, sinus-related symptoms and quality of life is not well established.⁷

Patients with CRS are known to have comorbidities. Chronic lung disease (CLD) i.e. bronchial asthma, COPD

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and chronic bronchitis are commonly associated with CRS. The unified airway concept where different parts of the upper and lower airways are affected by the same immunological mechanisms explains this association. However, underlying immune responses are not the only factor driving the multifactorial etiology of CRS. Beside the immune factors there are also genetic, environmental, occupational and anatomic factors which contribute to the manifestation of CRS. Other co-morbidities can be diabetes mellitus (DM), peripheral vascular disease (PVD), heart disease (HD) etc. But a real therapeutic challenge has been the severe chronic upper airway disease patients as they have uncontrolled CRS with disease related factors contributing to the severity of their disease as well as negative influence on the outcome of FESS.

In view of the above, this study was carried out to determine the prevalence and severity of various symptom manifestations of chronic rhinosinusitis as well as to compare the symptomatic relief of the patients following surgery by regular follow ups and by using grading systems.

This study also evaluated the impact of chronic lung disease on the outcome and complications of FESS.

Materials and Methods

This prospective longitudinal cohort study was carried out for 18 months' duration with 50 patients amongst the patients attending the OPD of Otorhinolaryngology with chronic Rhinosinusitis following inclusion and exclusion criteria.

Inclusion criteria – Male or female > 18 and <70 years of age

Prior conservative treatment of CRS for at least 12 weeks

No prior sinus surgery

Exclusion criteria – Any nasal pathologies like tumor or any growth

Any nasal structural abnormalities like Deviated Nasal Septum

Paediatric age group

Non-invasive fungal balls and invasive fungal disease

Pregnant or lactating women

A detailed history including associated CLD and other co-morbidities was documented. All the patients underwent clinical evaluation by Anterior Rhinoscopy and other associated examination of nose and throat followed by Diagnostic Nasal Endoscopy. All of them underwent X-ray as well as CT Scan of Nose and Paranasal Sinuses.

The study population underwent endoscopic sinus surgery. The extent of surgery was determined by the severity of disease and extent of involvement of sinuses as per the preoperative CT scan and nasal endoscopy.

Patients were evaluated 1 week, 2 weeks, 4 weeks, 8 weeks, 3 months, 6 months, 9 months and 1 yr after surgery. Nasal endoscopy was performed in each post-operative visit. CT scan was done 6 months and 1 year post-operatively.

Improvement of symptoms was assessed using the following scoring scale. Where, success is meant by

complete resolution of symptoms or improvement of symptoms (score +1) and cases with no change of symptoms (score 0) or deterioration of symptoms (score -1) are said to be failures within 1 year of follow-up.

Assessment was done subjectively using questionnaires about improvement or deterioration of the symptoms and objectively using nasal endoscopy.

Pre-operative symptom scores were calculated. The symptoms included were nasal obstruction, rhinorrhoea, smell dysfunction, nasal bleeding, headache, facial pain and others. Pre-operative scores were classified as: 0 – no symptoms, 1 – mild (symptoms causing little or no discomfort), 2- moderate (symptoms interfering daily activities but not sleep), 3- severe (symptoms affecting daily activities and sleep).

Post-operative scoring was done. They were: +1 (improved), 0 (no change), -1 (worse).

Post-operative success and complication rates were analysed.

Results

The mean age of this study population was 35.60 years with M: F ratio 1.27:1 [Table I].

Table I : Distribution of number of patients according to age

AGE IN YEARS	NUMBER OF PATIENTS	MEAN AGE IN YEARS
10-20	4 (8%)	35.6
21-30	15 (30%)	
31-40	14 (28%)	
41-50	12 (24%)	
51-60	4 (8%)	
60 and above	1 (2%)	

Table II : Distribution of patients according to post-operative symptoms score

SYMPTOMS	FAILURE		SUCCESS	SUCCESS RATE
	SCORE (-1)	SCORE (0)	SCORE (+1)	
Nasal obstruction	1	4	40	88.89%
Rhinorrhoea	2	7	34	79.07%
Headache	2	4	25	80.65%
Smell dysfunction	4	9	15	53.57%
Epistaxis	0	1	4	80%
Facial pain / pressure	1	4	15	75%

Table III : Distribution of study population according to outcomes of Co-morbidities (n=50)

CO-MORBIDITIES	SUCCESS	FAILURE	TOTAL
None	21 (65.63%)	11 (34.37%)	32
CLD	8 (66.67%)	4 (33.33%)	12
DM	1 (25%)	3 (75%)	4
PVD	1 (100%)	0	1
HD	0	1 (100%)	1

Table IV : Distribution of study population according Co-morbidities and Complications (n=50)

CO-MORBIDITIES	COMPLICATIONS	NO COMPLICATIONS	TOTAL
None	10 (31.25%)	22 (68.75%)	32
CLD	4 (33.34%)	8 (66.66%)	12
DM	2 (50%)	2 (50%)	4
PVD	1 (100%)	0	1
HD	0	1 (100%)	1

Majority of the patients presented with nasal obstruction (90%), Nasal discharge (86%) and headache in (62%). The success rates were highest for nasal obstruction (88.89%). All other symptoms also had high success rates except for hyposmia which was as low as 53.57% [Table II].

Among 50 patients, synechia occurred in 6 (12%), severe epistaxis in 5 (10%), facial odema in 1(2%) and orbital injury in 1 (2%) cases.

Among the 50 patients included in this study, we found OM unit pattern of disease in 21 cases, sporadic form in 13 cases, diffuse polyp in 10 cases, infundibular and spheno-ethmoidal pattern in 3 cases each. Among 21 cases of OM unit patterns, 13 (61.9%) were successful after FESS. In case of sporadic form 9 (69.2%), diffuse polyp form 6 (60%), infundibular form 1 (33.3%) and spheno-ethmoidal form 2 (66.7%) were successful.

In our study among 50 patients of chronic rhinosinusitis, 32 patients were otherwise healthy. Chronic lung disease (CLD) was found in 12 cases, diabetes (DM) in 4 cases, peripheral vascular disease (PVD) and heart disease (HD) in 1 case each. The success rates and complications in relation to the co-morbidities are detailed in Table III & IV.

Even after proper endoscopic sinus surgery, 4 (8%) cases had recurrence of disease within 1 year of follow-up.

Discussion

CRS is a common health problem that leads to frequent visit to primary health care and Otorhinolaryngologists. It contributes to the significant amount of health care expenditure due to direct cost arising from physician visit as well as indirect cost related to missed days of work and general loss of productivity due to worsened quality of life. Thus it is essential to evaluate the outcome and effectiveness of FESS in relieving the symptoms of CRS. Because the disease itself is defined by signs and symptoms, it is logical to use the presence and severity of sinonasal symptom as primary outcome measure.

The present study focused on the interaction between

patients' symptom profiles and hence QOL before and after FESS. As reported by Senior BA et al⁸ nasal obstruction, postnasal drip, and headache were the leading symptoms observed in the CRS population. In the present study, these symptoms were identified to be mainly responsible for worsened QOL. After FESS, a significant long-term improvement of both major symptoms and improvement in QOL was achieved in our patients.

One disadvantage of the present study was that the tool we used for outcome research was not validated before usage. However, health or QOL is not easy to measure. According to the World Health Organization, health is a "A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".⁹ The Chronic Sinusitis Survey has been developed based on duration of symptoms. Short Form 36-Item Health Survey (SF-36)¹⁰ is a general health evaluation tool that was not specifically designed for CRS, but it provides important information concerning the functional well-being of the individual and the evaluation of the overall response to treatment.¹¹ Another tool for the evaluation of the response to therapy is the Chronic Sinusitis Technology of Patient Experience (TyPE) Specific Questionnaire.¹² Furthermore, the Rhinosinusitis Disability Index was established, which consists of 30 items.⁸ Most of these evaluation tools have excellent validity and reliability.^{10,11}

Besides "subjective" measurements, the discussion of the best, most meaningful tools for treatment outcome control also includes "objective" methods. So we used both radiological (CT) and endoscopic examination for this purpose. As there is no exact measure of subjective improvement, patient satisfaction and symptomatic improvement was the objective of surgery.

This study is in agreement with the study conducted by Mishra D K et al¹³ where they found nasal obstruction, rhinorrhoea and headache as most common symptoms with comparable success rate for nasal obstruction. But for rhinorrhoea and headache, the current study has reported lower success rate.

Findings of Lt Col Nair Set al¹⁴ is similar to our study except that they have not reported any case with smell dysfunction.

Table V : Analysis of pre-operative systems and post-operative success in different studies

NASAL	NASAL OBSTRUCTION		RHINORRHOEA		HEADACHE		SMELL DYSFUNCTION	
	SYMPTOM (%)	SUCCESS (%)	SYMPTOM (%)	SUCCESS (%)	SYMPTOM (%)	SUCCESS (%)	SYMPTOM (%)	SUCCESS (%)
Netkovski et al	93.7	87	72.5	70.5	65	59.4	62.5	58.7
Bunzen et al	100	83.3	91.6	91.6	87.5	62
Nasser et al	76	69	63.5	48	74.4	59
Nair et al	86	87.2	90	78.1	91	82.4
Current study	90	88.9	86	79.1	62	80.7	56	53.6

Damm Michael et al¹⁵ has found similar success rates for all the symptoms as this study except higher success rate in case of hyposmia.

The study conducted by Netkovski J et al¹⁶ had lower success for both rhinorrhoea and headache and a slightly higher success for hyposmia [Table V].

This study is in agreement with Mishra D K, Bhatta R¹³ et al who also found that the osteomeatal (OM) unit pattern of disease was most prevalent followed by sporadic form of disease and sphenoid-ethmoidal disease. Lt Col Nair et al¹⁴ in their study also concluded that OM unit involvement was the most common pattern.

I Baumann, G Blumenstock, I M Zalaman¹⁷ et al in their study on impact of co-morbidities on quality of life in chronic rhinosinusitis showed that CLD had clear negative influence on symptoms and the post-operative result. In contrast, we have found no association between CLD and outcome as well as complications in FESS.

Because of small sample size in this study, there remains a chance of statistical error. Further prospective clinical studies with larger sample size are required to assess the long term outcomes of FESS but compliance for longer follow up remains a matter of concern.

Conclusion

The leading complaints of patients with CRS are nasal

obstruction with nasal discharge. FESS is highly effective treatment to relieve all major symptoms of CRS except smell dysfunction. This study also concludes that CLD has got no influence in the outcome and complications of FESS.

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A Cross Sectional Study of Assessment of Hearing in Infants of Gestational Diabetes Mothers

<https://doi.org/10.47210/bjohns.2023.v31i2.939>

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ABSTRACT

Introduction

Hearing loss is one of the most prevalent congenital disorders in infants. Neonatal hearing screening is an important tool for early detection of hearing impairment in newborns. Present study is aimed to assess the impact of hearing among babies born to gestational diabetic mothers.

Materials and Methods

This study was conducted among 100 pregnant mothers who gave birth in Obstetrics and Gynaecology Department in a medical college in Pondicherry from December 2020 to July 2022. 50 pregnant women with gestational diabetes mellitus (GDM) were assigned to Group 1 and 50 pregnant women who had no GDM were assigned to Group 2. Hearing screening among the infants were done using Otoacoustic emissions and Brainstem evoked response audiometry (OAE and BERA). The results in Group 1 and Group 2 were collected, analysed and compared.

Results

All patients were between 20 – 45 years of age. The average gestational age was 39.2 ± 5.7 from 36 weeks to 42 weeks. In the present study OAE has shown that 40% babies had bilateral refer and 18% had unilateral refer in GDM mothers which was significantly higher than the normal mothers. BERA showed that 14% had hearing loss among those of the GDM mothers which was significantly higher than the normal mothers. Comparison of abnormal hearing screening between the two groups were significant ($P < 0.05$).

Conclusion

Gestational diabetes mellitus increases the risk of hearing impairment in newborns. Timely detection and standardised management should be followed and early intervention procedures should be studied and developed.

Keywords

Infant; Hearing loss; Pregnancy; Audiometry, Evoked Response; Diabetes; Gestational

Neonatal hearing screening is an important tool for early detection of hearing impairment in newborns. Gestational diabetes is a metabolic disease that can occur in pregnancy and cause

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complications similar to other diabetic patients.¹ Gestational diabetes is a metabolic disorder that can emerge during pregnancy and produce consequences similar to those seen in other diabetics.¹ Hearing loss is one of the most prevalent congenital disorders in infants. 1.4 out of every 1000 newborns had a bilateral congenital hearing impairment.² The main objective of treatment for gestational diabetes mellitus is to avoid complications. There is only weak evidence that gestational diabetes increases the likelihood of cochlear damage and hearing loss in foetuses, despite the fact that diabetes mellitus usually results in hearing loss.^{1,3-5}

The present study was conducted to find the hearing

status in infants of diabetic mother and non diabetic mother.

Materials and Methods

This Prospective comparative study was conducted from December 2020 to October 2022, after getting ethical clearance from AVMC research committee.

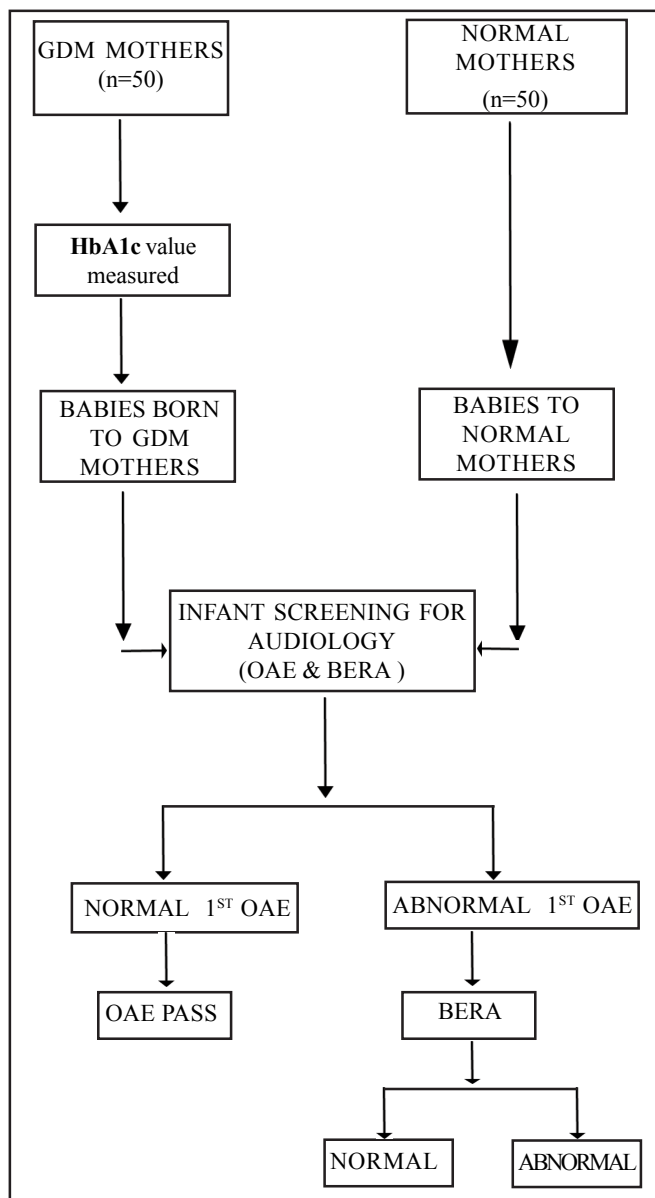


Fig 1. Showing the study methodology

The study included two groups of 50 pregnant women each. One group included normal pregnant women (n=50), and other group included women who are diagnosed with gestational diabetes mellitus. After getting an informed and written consent from the patients, detailed history, clinical assessment and blood investigations were done. Their HbA1c values and OGTT values were recorded. The babies born in both the groups were sent for hearing screening (OAE). Those babies who failed the screening test were subjected for BERA, after 15-20 days.

Mothers with previous history of diabetes, and babies with risk factors like low APGAR, LBW, meningitis, ototoxic drugs, intrauterine infections, and any other congenital deformities were excluded from the study.

According to the OGTT criteria, at least one deranged value of the 0, 1, and 2nd hour (>92, 180 and 153 mg/dl) is diagnosed as GDM[6] and according to the WHO guidelines, HbA1c values more 48 mmol/mol (6.5%) is considered as diagnosis for GDM.⁶

Sample size calculation: Formula $4pq/d^2$

$p = 9.1$; $q = 1-p$; $q = 90.9$. Error rate (d) = 5

Therefore, the sample size calculated by using the formula is 100

The sample size 100 (50 in each group) was calculated based on the statistical formula for comparison of two proportions with the expected proportion of hearing loss of infants among gestational diabetic and normal mothers were 0.41 and 0.08 respectively. The level of significance and power were taken as 5% and 90% respectively. 10% of non response rate was considered. A similar study by Yildiz E G et al was taken as reference.⁷

HbA1c is done in the department of Biochemistry.

OAE and BERA is available in audiology block which is already routinely carried out in all neonates as a screening procedure.

Results

In this present study a total of 100 pregnant women were selected who fulfilled the inclusion criteria. The mean age was between 20 – 45 years of age, with an average

age of 30.0 ± 5.4 years old. The average gestational age was 39.2 ± 5.7 from 36 weeks to 42 weeks. Both group of newborns delivered by vaginal delivery and caesarean delivery were included. Among the babies of 50 gdm

mothers, 8 babies (7.82%) showed BERA variations, and among 50 babies of normal mothers, 3 babies (4.64%). Comparison of abnormal hearing screening between the two groups are significant different ($P < 0.05$).

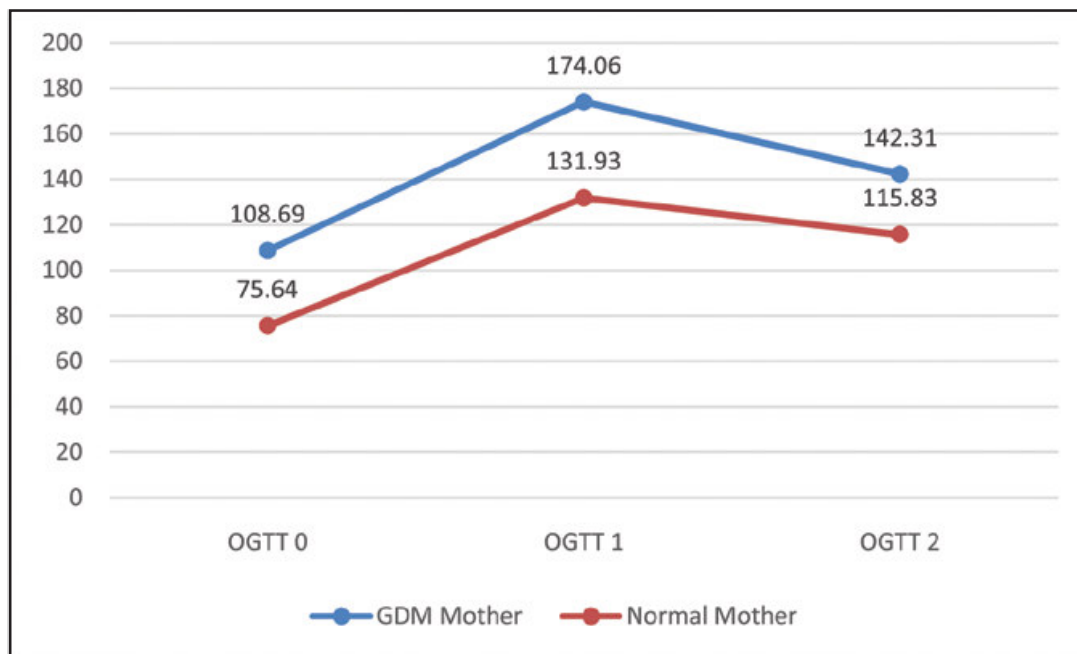


Fig. 2. OGTT among the study participants

Table I : Glucose Challenge test among the study participants

VARIABLE	GDM MOTHER		NORMAL MOTHER		P VALUE
	MEAN	SD	MEAN	SD	
GCT	296	97.44	131.13	9.43	<0.001

Table II: HbA1c among the study participants

VARIABLE	GDM MOTHER		NORMAL MOTHER		P VALUE
	MEAN	SD	MEAN	SD	
HbA1c	6.68	0.59	5.53	0.35	<0.001

Table III: OAE among the study participants

OAE	GDM MOTHER		NORMAL MOTHER		P VALUE
	N	%	N	%	
B/L Pass	21	42	34	68	
B/L Refer	20	40	8	16	
L- Pass R- Refer	3	6	2	4	
R- Pass L- Refer	6	12	6	12	0.038

Table IV: BERA among the study participants

BERA	GDM MOTHER		NORMAL MOTHER		P VALUE
	N	%	N	%	
B/L Minimal HL	1	2	0	0	
B/L Moderate HL	4	8	1	2	
B/L Normal	42	84	49	98	
R Minimal HL	1	2	0	0	
L Moderate HL	1	2	0	0	<0.001

Discussion

According to the World Health Organization, 466 million individuals worldwide suffer from hearing loss that is debilitating. The World Health Organization (WHO), where hearing loss is developing as a serious health problem, predicts that over 1 billion young individuals are at risk of the condition.⁸

According to estimates, 463 million individuals (20-79 years) have diabetes, and the frequency of the disease rises with ageing.⁹ Surprisingly, 231 million persons with diabetes do not know they have the disease.⁹ Diabetes has been associated with a number of illnesses, including atherosclerosis, which results in kidney disease, retinopathy, neuropathy, and cardiovascular disease. It has been difficult to prove a direct causal relationship

between inner ear disease with accompanying hearing loss and the failure of the insulin/glucose signalling that characterises type 2 diabetes.¹⁰

Some types of hearing loss may be accompanied with diabetic micro-angiopathy in the ear, and both type 1 and type 2 diabetic individuals have been shown to have cochlear alterations. Diabetes resulted in much thicker vascular walls in the stria vascularis and basilar membrane compared to healthy people, as well as a loss of outer hair cells in the basal turns.¹¹ The beginning of microvascular disease, which comprises thickening of the basement membrane, pericyte degeneration, and endothelial cell hyperplasia, seems to be influenced by endothelial dysfunction.

It has recently been shown in the Nurses' Health Study II Study that maintaining a healthy diet is associated with

a lower incidence of hearing loss.¹² Participants who continued a Mediterranean-style diet or meals low in packaged food and high in dietary fibre showed a decreased incidence of hearing loss when they were examined more than 20 years later. Women who scored in the top 20th percentile for all dietary factors tended to be older, leaner, physically active, and non-smokers.¹² It is well acknowledged that there is a link between hearing loss and the both type 1¹³ and type 2¹⁴ diabetes, and that this link is unaffected by the type of diabetes, according to a meta-analysis that included cohorts of patients with both types of diabetes.¹⁵

In the present study OAE has shown that 40% and 18% had bilateral and unilateral refer in GDM mothers which significantly higher than the normal mothers. In BERA it was shown that 14% had hearing loss among those of the GDM mothers which was significantly higher than the normal mothers. Similarly in a study done Gulen Yidiz,⁷ it was shown that initial hearing screening test was unsuccessful in twenty (40.8%) neonates in the GDM group and five (7.7%) neonates in the non GDM group ($p = .001$). At the first screening, the proportion of neonates in the GDM group with bilaterally unsuccessful hearing screening tests was greater (75% vs. 20%). The second TEOAE hearing screening test was unsuccessful in 15 (75.0%) of 20 neonates in the GDM group and 1 (20.0%) of 5 neonates in the Non GDM group. This is in accordance with the study done by Padmadasan S et al and Zhou JH et al.¹⁶

Conclusion

This research showed that GDM affects neonates' hearing. Blood glucose levels should be controlled for high-risk populations, combined with quick intervention, standardised therapy, a reasonable diet, and sufficient physical activity. The development of early intervention programmes and the reinforcement of the necessary screening and follow-up procedures are both necessary.

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Taste Dysfunction In COVID-19 Patients; A Cross-Sectional Observational Study

<https://doi.org/10.47210/bjohns.2023.v3i2.898>

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ABSTRACT

Introduction

It has been observed that olfactory dysfunction (anosmia, hyposmia and parosmia) and gustatory (taste) dysfunction (ageusia, hypogeusia and dysgeusia) are one of the classical presentations of COVID-19. Gustatory (taste) dysfunction attributable partly to loss of retro-nasal olfaction (which adds to the flavour, a component of taste sensation) while eating or drinking food.

Materials and Methods

It is a cross sectional observational study involving COVID-19 patients aged between 18 to 100 years. Taste dysfunction was analysed and compared with various inflammatory markers and sino-nasal symptoms.

Results

In this time bound study, 61.88 % of the study participants were male and 38.13 % were females. Majority of the participants were in the age group between 20 and 60 years. Fifty four (33.75%) developed gustatory dysfunction in the form of ageusia/hypogeusia. Among the individuals with ageusia/hypogeusia, majority of the patients (n=26) (48.15%) complained of 50-75% loss of taste sensation followed by 50-75% loss of taste sensation in fourteen (25.93%) patients. Mean duration of ageusia/hypogeusia among 54 patients was 9.33 ± 4.13 days. There was no statistically significant association between gustatory or taste dysfunction with serum inflammatory markers except serum ferritin levels. There was significant relationship between presence sino-nasal symptoms and development of taste dysfunction.

Conclusion

Ageusia (hypogeusia) was found in significant proportion of patients with COVID-19. These symptoms also contribute to significant proportion of depression and low confidence and results in poor nutrition and subsequent nutritional deficiencies which may lead to long Covid syndrome.

Keywords

Taste disorders; Ageusia; Coronavirus; Smell

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a highly infectious novel coronavirus leading to Coronavirus disease 2019 (COVID-19).^{1, 2} The disease was first detected in December 2019 in Wuhan seafood market, China. Being

highly infectious, this virus caused the deadly pandemic leading to millions of individuals being infected and has killed lakhs of people across the globe. Fever, cough and breathlessness along with constitutional symptoms like fever and myalgia are the classical symptoms of COVID-19.^{3, 4, 5}

It has been observed that olfactory dysfunction (anosmia, hyposmia and parosmia) and taste dysfunction (ageusia, hypogeusia and dysgeusia) are one of the classical presentations of COVID-19. It has been observed that anosmia coincides with the occurrence of taste dysfunction (TD) manifesting as ageusia or

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hypogeusia and is attributed to loss of retro-nasal olfaction (which adds to the flavour, a component of taste sensation) while eating or drinking food.⁶ Although the exact mechanism is not known it is found now that there are ACE-2 (Angiotensin Converting Enzyme-2) receptors present on the gustatory epithelium which may act as the receptors for SARS-CoV-2.⁷

The need for the study: Taste dysfunction is one of the early symptoms of COVID-19 and has been considered not only troublesome for oral nutrition but also a contributor of the significant proportion of depression in COVID-19. However, the prevalence of taste dysfunction varies widely as reflected by the results of various studies. It is important to recognize these symptoms early so that the infected person can be diagnosed, isolated and treated early. Hence, this study was undertaken to know the prevalence of taste dysfunction in patients admitted to tertiary care hospital.

Primary objective of the study was to find the prevalence of taste dysfunction and sino-nasal symptoms in patients with COVID-19.

Secondary objectives of the study was to (i) find the

relationship between classical symptoms of upper respiratory viral infection (rhinorrhea, nose block and headache) with the occurrence of taste dysfunction (ii) find the relationship between taste dysfunction and markers of inflammation in COVID-19.

Materials and Methods

This was a cross-sectional study involving all admitted patients with COVID-19. The diagnosis of COVID-19 was made by either of the following

- Presence of SARS-CoV-2 RNA detected by reverse transcription polymerase chain reaction (RT-PCR) in the nasopharyngeal or oropharyngeal swab specimens&/or
- Positive Rapid Antigen Test for SARS-CoV-2.

The diagnosis was made based on the interim guidelines issued by the ministry of health and family welfare (MOHFW), Government of India.

Patients with COVID-19 were classified based on the severity into 3 categories as per Indian Council of Medical Research (ICMR) (Table I).

Table I : COVID-19 disease category based on severity according to ICMR

CATEGORY	CRITERIA
GROUP A	<ul style="list-style-type: none"> ● Asymptomatic or patients with mild symptoms. ● Respiratory rate less than 24 per minute and ● Oxygen saturation (SpO₂) more than 94% in room air.
GROUP B	<ul style="list-style-type: none"> ● Symptomatic patient with mild to moderate pneumonia with no signs of severe disease. ● Respiratory rate 24 to 30 per minute and SpO₂ 90% - 94% in room air.
GROUP C	<ul style="list-style-type: none"> ● Symptomatic patient with severe pneumonia with any of the following <ul style="list-style-type: none"> ■ Respiratory rate more than 30 per minute ■ SpO₂ less than 90% in room air or less than 94% with oxygen ■ Acute respiratory distress syndrome (ARDS) ■ Septic shock

All patients admitted were screened for sino-nasal symptoms and taste dysfunction at the time of admission after obtaining the written informed consent. The duration of each symptom was recorded. Patients were followed up until their discharge from the hospital or until death due to COVID-19. Time taken for recovery from TD was recorded.

This was a cross sectional study with universal sampling technique adopted to all the consecutive COVID-19 patients admitted between 25/08/2020 to 25/11/2020. There were no interventions or drug trial involved in this study. Institutional ethical committee clearance was obtained.

Inclusion criteria was all patients with COVID-19 aged between 18 to 100 years admitted to KVG medical college and hospital. Exclusion criteria were (i) patients who did not give consent to participate in the study (ii) patients with pre-existing taste abnormality (due to any etiology).

Following history were recorded to assess sino-nasal symptoms: Running nose/nasal discharge, nose block, headache/facial pain, excessive sneezing, nasal itching, post-nasal drip.

Following definitions were used in the assessment of taste dysfunction (TD): (a) Ageusia: total loss of taste sensation (b) Hypogeusia: reduced but intact taste sensation (c) Parageusia: altered taste sensation. No objective taste measurement tools were used and all the above symptoms were based on the subjective reporting by study participants. However, severity of loss or reduction of taste sensation was graded as less than 25% loss, 25 to 50% loss, 50 to 75% loss and more than 75% loss of taste sensation as reported by study participants. Similarly, no objective measurement scales were used for quantification of loss of smell or alteration of smell.

Following data were collected: (i) Demographic details: Age, gender (ii) Comorbid medical conditions (iii) Sinonasal symptoms related to COVID-19 (iv) Taste symptoms (as mentioned above) (v) Investigations- Haematological parameters like Complete blood count, Renal function tests (serum creatinine, blood urea), liver function tests (serum bilirubin, serum albumin, total protein, transaminases), blood sugars [Random blood sugar (RBS), glycosylated hemoglobin percent (HbA1c)], inflammatory

markers [C-reactive protein (CRP), serum ferritin, Lactate dehydrogenase (LDH), D-dimer].

For statistical analysis, the data was entered in Microsoft office Excel 2007 and SPSS version 21 was used for analysis of data. The prevalence of sino-nasal dysfunction and taste dysfunction was calculated. The relationship of these symptoms was correlated with the disease inflammatory markers. The data was shown in the form of percentages and means. Chi-square test & t test was used for analysis.

Results

This cross sectional study included 160 patients diagnosed with COVID-19. In this time bound study, 61.88 % of the study participants were male and 38.13 % were females. Majority of the participants were in the age group between 20 and 60 years. The mean age of male study participants was 44.96 ± 16.28 years, and that of female study participants was 43.75 ± 16.78 years. The mean age of the whole study population was 44.50 ± 16.43 years (Fig. 1).

Hypertension and Diabetes mellitus were the most common comorbid conditions in the study accounting for 25% and 20.62% respectively. 80 (50%) of the study participants did not have any identifiable comorbid conditions (Table II).

In this study we categorized the Covid-19 patients in 3 disease severity category as per ICMR protocol (category A, B & C). This categorization is based on the in-hospital follow up. The participants who were initially in category A and later progressed to category B were included in category B for the analysis. We, observed that majority of the patients (n=107) belonged to category B, accounting for 66.87%. Forty three (26.87%) and ten (6.25%) of patients belonged to category A and C respectively (Fig. 2).

The baseline hematological and biochemical parameters are analysed. The mean vitamin D3 levels in the study was 16.38 ± 9.12 ng/mL which is the deficiency range. The mean CRP level was 19.31 ± 43.88 mg/L which is more than the normal upper limit (10mg/L). The mean LDH level was 406.42 ± 127.55 IU/L which is also

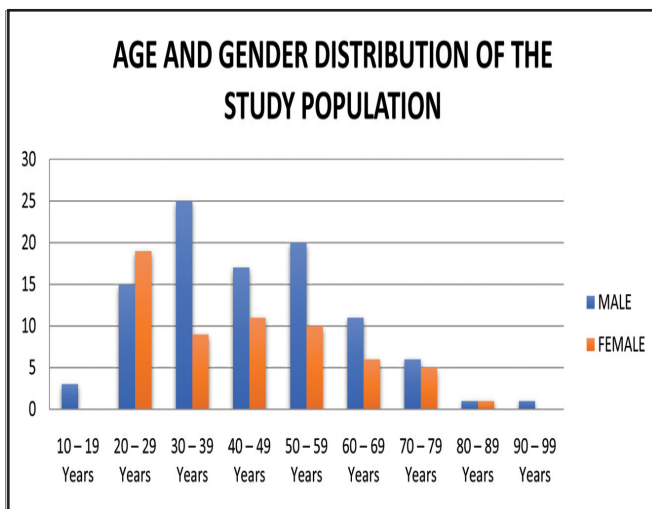


Fig. 1. Bar diagram of age and gender distribution of study population

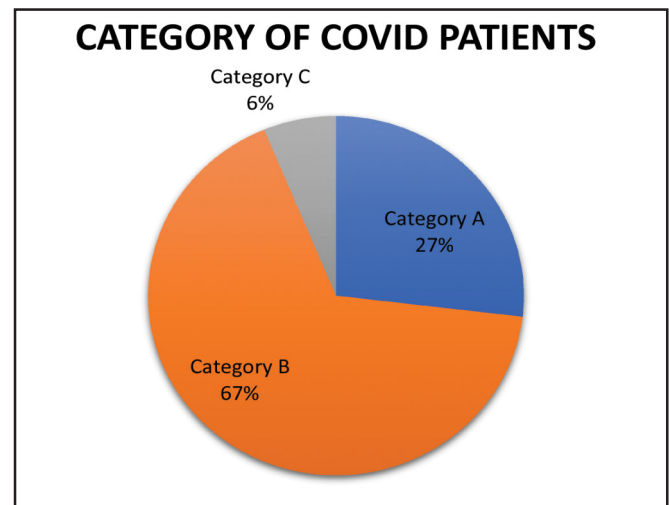


Fig. 2. Distribution of patients among category A, B and C severity group

Table II: Comorbidities in the study population

SL. NO.	COMORBIDITIES	NO. OF PATIENTS NO. (%)
1	Hypertension	40 (25%)
2	Diabetes Mellitus	33 (20.62%)
3	Hypothyroidism	4 (2.5%)
4	Ischemic heart disease (IHD)	1 (0.62%)
5	Maturity onset diabetes of young (MODY)	1 (0.62%)
6	Supraventricular tachycardia (SVT)	1 (0.62%)
7	No Comorbidities	80 (50%)

beyond the normal range (105-333 IU/L). The mean D-dimer level was 0.59 ± 1.03 g/L which is slightly above the normal upper limit (0.5 g/L). These observations suggest that there is significant inflammation in patients with Covid-19 across all categories of severity.

In this study, we collected serial values of CRP, serum ferritin levels, serum LDH 1 levels and D-dimer levels (which were done as per protocol of the ministry of health

and family welfare). At least 3 values of the above mentioned parameters were collected. It was observed that there was improvement in the serial CRP levels as compared to D-dimer and serum ferritin levels. However, there was no significant change in the serial LDH 1 levels.

Among the sino-nasal symptoms headache was the most common symptom which was seen in twenty three (14.37%) study participants. The mean duration of headache was 7 ± 3.68 days. Thirteen (8.12%) patients had running nose and five (3.12%) had nose block. The mean duration of running nose and nose block was 5.69 ± 2.56 days and 9.4 ± 5.94 days respectively.

Fifty four (n=54) (33.75%) developed gustatory dysfunction in the form of ageusia or hypogeusia. Among the individuals with ageusia/hypogeusia, majority of the patients (n=26) (48.15%) complained of more than 75% loss of taste sensation followed by 50-75% loss of taste sensation in fourteen (25.93%) patients. Mean duration of ageusia/hypogeusia among 54 patients was 9.33 ± 4.13 days (Table III).

The mean CRP level among patients with TD is 20.49 ± 52.65 mg/L as compared to 18.70 ± 38.92 mg/L among patients without TD. This was not statistically significant ($p=0.8081$) (Table IV).

The mean ferritin level among patients with TD is

Table III: Severity of symptoms in patients with COVID-19

SNO.	SEVERITY OF SYMPTOMS (% of loss of taste sensation)	AGEUSIA/HYPOGEUSIA NO. (%)	MEAN DURATION OF SYMPTOMS (in days)
1	< 25 %	6 (11.11 %)	6.83 ± 2.31
2	25 – 50%	8 (14.81%)	8.37 ± 6.02
3	50 – 75 %	14 (25.93%)	10.21 ± 3.35
4	> 75%	26 (48.15%)	9.73 ± 4.09

Table IV: Taste dysfunction in COVID-19 patients belonging to different categories

GUSTATORY DYSFUNCTION	MEAN CRP (mg/L)	MEAN FERRITIN (mcg/L)	MEAN LDH (IU/L)	MEAN D DIMER (g/L)
Category A				
Gustatory dysfunction	19.34 ± 70.41	199.47 ± 260.24	403.95 ± 93.78	0.29 ± 0.19
No Gustatory dysfunction	17.02 ± 41.71	164.57 ± 163.72	403.32 ± 162.89	0.59 ± 1.60
T Value	0.1349	0.5372	0.0150	0.8243
p Value	0.8933	0.5940	0.9881	0.4145
Category B				
Gustatory dysfunction	22.34 ± 42.86	240.72 ± 304.66	416.62 ± 99.11	0.45 ± 0.35
No Gustatory dysfunction	14.10 ± 24.48	152.54 ± 165.13	393.08 ± 129.27	0.45 ± 0.44
T Value	1.2570	1.9341	0.9204	0.0117
p Value	0.2115	0.0558	0.3595	0.9907
Category C				
Gustatory dysfunction	8.01 ± 7.82	731.87 ± 562.81	592 ± 151.63	0.7 ± 0.79
No Gustatory dysfunction	73.81 ± 92.90	223.16 ± 204.60	440.57 ± 130.79	3.53 ± 2.05
T Value	1.1837	2.2168	1.6100	2.2470
p Value	0.2705	0.0575	0.1461	0.0548

253.49 ± 321.47 mcg/L as compared to 159.93 ± 166.71 mcg/L among patients without TD. This was statistically significant ($p=0.0163$) (Table IV).

The mean LDH-1 level among patients with TD is 421.90 ± 106.63 IU/L as compared to 398.53 ± 136.79 IU/L among patients without TD. This was statistically not significant ($p=0.2744$) (Table IV).

The mean D-dimer level among patients with TD is 0.41 ± 0.34 g/L as compared to 0.69 ± 1.23 g/L among patients without OD. This was statistically not significant ($p=0.1043$) (Table IV).

We compared the inflammatory markers like CRP, serum ferritin, serum LDH-1 and D-dimer in patients with and without taste dysfunction across all three disease category (category A, B & C). There was no statistically significant association between gustatory or taste dysfunction with any of the above serum inflammatory markers (Table IV).

A total of 54 patients (prevalence = 33.75%) developed taste dysfunction. 10.62% of the patients with sino-nasal symptoms developed taste dysfunction and there was significant relationship between presence sino-nasal symptoms and development of taste dysfunction.

Discussion

In a meta-analysis of 3563 patients with COVID-19 infection, it was found that the mean prevalence of self-reported loss of smell to be 47%.⁸ Moein *et al.* demonstrated that 98% of the hospitalized study participants ($n=60$) had some degree of OD on formal testing, whereas only 35% had self-reported loss of smell or taste. Hence, formal testing for OD and TD is more accurate than just relying on self-reporting of the symptoms.⁹

In a metaanalysis, 32,918 patients out of 138,785 patients had TD.¹⁰ Taste dysfunction may last for months with very little improvement after about two months.^{11,12} Hence, TD has considered as one of the harbinger of long COVID syndrome.

One of the proposed mechanism of TD is the binding

of SARS-CoV-2 to angiotensin converting enzyme-2 receptors in the salivary glands leading to impaired salivary flow.¹³ There is limited literature available on the correlation between TD and the COVID-19 disease severity.

In a metanalysis, it was found that 78.8% of patients had taste recovery at 30 days, 87.7% at 60 days, 90.3% at 90 days, and 98.0% at 180 days, with median recovery time of 12.4 days.¹⁴

In our study, mean duration of ageusia/hypogeusia among 54 patients was 9.33 ± 4.13 days. As mentioned earlier we could not follow up the patients until complete recovery of the taste perception.

ACE2 receptors are expressed highly over tongue than other parts of oral cavity and this may be the likely reason for taste dysfunction. ACE2 receptors are also expressed on various cells of the body (glial cells and neurons in the brain, alveolar epithelial cells, gut, kidney and myocardium).^{15, 16}

There is no data on the pharmacological or non-pharmacological interventions to improve the taste dysfunction.

Following are the limitations of the study:

1. The assessment of TD was subjective.
2. Objective examination to detect specific modality of taste dysfunction was not carried out.
3. Long term follow up of the patients is not done to know the average time taken for complete recovery from TD.
4. Effect of these symptoms on the quality of life and mental health is not evaluated.
5. The effect of medications on the occurrence and severity of TD is not evaluated.

Conclusion

Ageusia (or hypogeusia) was found in significant proportion of patients with covid-19. These symptoms also contribute to significant proportion of depression and low confidence and results in poor nutrition and subsequent

nutritional deficiencies which may lead to long Covid syndrome.

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Molecular Resonance Generator (MRG) Assisted Tonsillectomy-An Innovative Technique

<https://doi.org/10.47210/bjohns.2023.v31i2.786>

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ABSTRACT

Introduction

Dissection and Snare method of tonsillectomy was first introduced nearly a century ago. Since then several methods of performing tonsillectomy have evolved like electrocautery, harmonic scalpel, Laser, coblation and Magnetic Resonance Generator (MRG). All these methods have been used with the aim of overcoming the shortcomings with the previous methods like intra and post operative bleeding, reducing the duration of surgery and post operative pain. MRG works on the principle of quantum resonance and it has helped in minimizing the intraoperative and post operative bleeding as well as post operative pain. In this study MRG was used for tonsillectomy with favourable outcome.

Materials and Methods

12 patients who underwent tonsillectomy by MRG were included in the study. Various parameters like duration of surgery, intra and post operative bleeding and post operative pain were recorded and compared with other studies.

Results

In all the 12 patients favourable outcome was recorded. None of the cases had post operative bleeding and there was minimal intraoperative bleeding. Post operative pain showed a decreasing trend with very minimal post operative pain on day 3.

Conclusion

Our study highlights the advantages of MRG in tonsillectomy which nearly overcomes the drawbacks and complications encountered with other methods employed for tonsillectomy.

Keywords

Tonsillectomy; Complications; Magnetic Resonance Generator

Over the last two decades there has been several innovations and developments in the surgical methods employed for tonsillectomy, one of the most commonly done surgeries in otorhinolaryngology.

Ever since the introduction of first method of doing tonsillectomy-the Guillotine method, there has been a stupendous stride in newer methods constantly evolving. Conventional method of dissection and snare has been the longest in use for over a century, first described in 1909. Other methods like electro cautery, harmonic scalpel, laser, coblation and Molecular resonance generator (MRG) have since evolved and each of these,

have been used with an attempt to make the surgery least morbid with closer to minimal or no complications at all.^{1,2,3} Several authors have extensively published their experiences with these various methods elaborating the advantages of one over the other in the last few years.

Needless to say, the question then arises as to why

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despite there being several time tested methods still there is relentless research into developing newer and newer technologies for performing the surgery. We believe what can partly summarise the justification for this, is the infallible human endeavor to find that one robust technique, which can supersede almost all the shortcomings of the preceding methods, with maximum emphasis on almost nil intraoperative bleeding and mild to nil post operative pain.

Molecular resonance generator (Fig. 1) operates on the principle of quantum science and initially introduced in neurosurgery has steadily found its application in otorhinolaryngology especially in tonsillectomy.^{4,5}

Quantum molecular resonance (QMR) in MRG is generated by means of alternate current, high-frequency electron waves, characterized by a precisely and well-defined major wave at 4 MHz, followed by subsequent well-defined 8, 12, and 16 MHz waves with decreasing amplitudes. Electron energy quanta (EEQs) are thus obtained and calibrated for human tissue. As these EEQs are delivered, cell molecular bonds are posed to resonance- the QMR- and subsequent bond breakage occurs with minimal rise in temperature.^{4,6}



Fig. 1. Molecular resonance generator

Materials and Methods

It is a prospective, single blind, randomized study. 12 patients were included in the study done at a tertiary care centre. simple randomization method was used, where in patients considered fit for tonsillectomy were assigned numbers from one onwards and the odd ones were

selected for MRG assisted tonsillectomy. This helps in avoiding selection bias.

Single blind study enabled that patients did not know which method was used so as to ensure the patients response post operatively is not biased based on method of surgery especially for parameters like post operative pain.

The Aims Objective is to study the efficacy of MRG assisted tonsillectomy by considering the following parameters :-

- a) Intraoperative and postoperative bleeding
- b) Post operative pain
- c) Duration of surgery

Twelve patients, both males and females between 6 yrs to 30 years of age, who underwent tonsillectomy by MRG, were selected and included in the study, and following patients were excluded from study.

1. Patients who underwent adenoidectomy with tonsillectomy in the same sitting.
2. Patients in whom MRG was combined with other methods like conventional or coblation during the same surgery.

Signed informed consent was taken from the parents of pediatric age group patients and in adult patients, consent was sought from the patient themselves. All the surgeries were performed by experienced senior surgeon. Visual analogue scale was used for assessing the post operative pain. Pain assessment was done immediately after surgery, after twenty four hours of surgery and after three days postoperatively. Score 0 indicating no pain and 10 indicating agonizing pain. This method was used effectively, as all the patients could understand instructions well including the youngest patient in our series who was of 6 years.

Intraoperative bleeding was recorded by calculating number of soaked cotton swabs and suction collection at the end of surgery.

Duration of surgery is recorded by measuring the time from start of procedure till the end of the procedure.

Results

Total 12 tonsillectomies performed by MRG were included in the study. Indications were either chronic tonsillitis or obstructive tonsillar hypertrophy.

Majority were males (M:F ratio 2:1). Maximum were in 10 and 11 age group (50%) followed by children in 1 to 10 yr age group (44.4%). (Table I)

Table I: Age distribution of patients

AGE GROUP (IN YEARS)	NUMBER OF PATIENTS
1 - 10	5 (2 Patients of 8 yrs each, 2 patients of 7 yrs each and 1 patient of 6 yrs)
10 - 20	6 (4 patients of 10yrs each and 2 patients of 11 yrs each)
20 - 30	1 (26yrs)

Intraoperative and post operative bleeding - The average blood loss in MRG was 6.5ml intraoperatively and in none of the cases post operative bleeding was reported.

The average post operative pain score was 2.66, 1.58 and 1.42 in immediate post operative period, day 1 post operative and day 3 post operative respectively, thus suggesting a decreasing trend over 3 days, when the need for analgesic was almost nil. Even the immediate post operative pain score was minimal. (Fig. 2)

Minimal instruments used in MRG assisted tonsillectomy- Only 2 instruments –Boyle Davis mouth gag with tongue blade and tonsil holding forceps were used in performing the surgery while the MRG probe tip was enough for incision, dissection, cutting and coagulation whereas the conventional method requires an array of instruments.

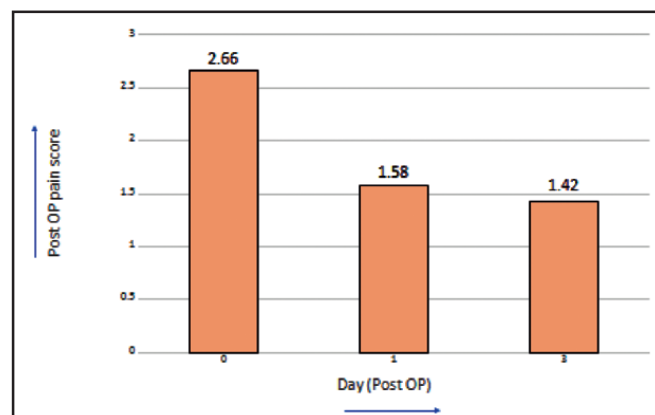


Fig. 2. Post operative pain score

Discussion

Tonsillectomy as a surgical procedure has seen introduction of many newer methods over the last few decades. In the current era where the digital platform provides over and excess information to the patients about the medical conditions, treatment options and the latest developments enabling them to seek better options with least complications, it is imperative for the otolaryngologist to be able to understand the pros and cons of all the current methodologies of performing tonsillectomy. This helps the patient as well as enables the ENT surgeon to choose the most suitable and judicious option amongst the spectrum of choices.

Traditionally the dissection & snare method for tonsillectomy has remained popular over the years. Cohen and Ernst first described the dissection and ligation method of tonsillectomy in the year 1909.⁷ Over the years use of electrocautery gained popularity as it helped to overcome complications like bleeding to a large extent and also reduced the operative time.^{8,9} But higher thermal tissue trauma with electrocautery with the cautery tips reaching temperature as high as 400 to 600 degree centigrade with monopolar and 150 to 200 degree centigrade with bipolar resulted in increased severity of post operative pain.^{8,10} Ever since there has been a relentless pursuit to develop methods which could overcome this drawback as well.

Hence the application of newer methods like Coblation and MRG paved the way for better outcomes. Coblation

method operates at low temperatures (60 to 70 degree centigrade) and therefore causes lesser tissue thermal injury and less post-op pain.⁷ Molecular resonance generator, causes even lesser temperature rise (<45 degrees).⁹ The principle of MRG is to break the molecular cell bonds without causing cell death or tissue vaporization.^{11, 12, 8}

MRG though popular & widely used in neurosurgery, its application in otolaryngology has remained limited and therefore not much literature elaborating its effectiveness.

The main reason we believe could be, due to lack of its cost effectiveness and hence not being available widely.

What prompted us to present our experience with MRG assisted tonsillectomy in a tertiary centre is the promising outcome in nearly hundred percent of the patients.

The intraoperative bleeding in our series was minimal (6.5 ml), which is comparable to the study by Riccardo D'Eredita et al. The mechanism of coagulation unlike in cautery is -it breaks the molecular bond, triggers proteic fibrinogenic denaturation and this activates a physiologic coagulation cascade without the formation of necrotic plug.^{4, 5}

In our study none of the patients reported post operative bleeding, whereas in the study by Riccardo D'Eredita using MRG, one patient had post operative bleeding after twenty four hours of surgery.

Post operative pain - In our series there has been a declining pattern of pain severity from immediate post op period till day 3. In immediate post op period pain was moderate in severity which reduced to mild by day 3. This is a striking feature of MRG which gives it a remarkable edge over other methods. In studies by Temple RH et al & Timms MS et al, in which coblation assisted tonsillectomy was done and in a study by Wexler D B in which electrocautery was used, an increasing pain severity by day 4 was reported. The reason for increasing pain severity in these methods is believed to be due to detachment of eschar from the tonsillar fossa, exposing muscle fibers & nerve endings previously sealed. MRG however owing to minimal thermal injury & therefore

reduced eschar formation and detachment does not cause increase in severity of pain. Our findings are comparable to the study by Riccardo D'Eredita et al.⁹

The average time taken in our study for MRG assisted tonsillectomy is 18mins, whereas in the study by D'Eredita et al, the average time duration was 9.5min with MRG, which is almost half the time taken for coblation assisted surgery in their series.

In our study increased time taken is possibly due to exposure to this new technology for the first time at our institute.

Besides tonsillectomy MRG has extended application in otolaryngology like in adenoidectomy, thyroid & ear surgeries.

Though the cost of MRG is still a limiting factor but considering the favorable outcome with this technique, which remains incomparable with other techniques, MRG certainly has an edge to gain momentum with time.

However if more and more literature is made available by different authors with their experience with MRG it will certainly help much more to boost its application potential.

Conclusion

In conclusion our study highlights the advantages of MRG in tonsillectomy which owing to its unique mechanism has enabled the possibility of nearly overcoming the drawbacks and complications of other surgical methods used in tonsillectomy.

Besides closer to nil complications and very minimal post operative pain and bleeding, this method considerably lessens the duration of surgery & also the need for instruments is minimal.

In this era of ever growing demand for painless & bloodless surgery, MRG has the potential to have a strong foothold in its application in tonsillectomy.

As with introduction of any new technology more experience is gained by operating large number of cases, which definitely helps to bring out better surgical outcomes, MRG too we believe is no exception to the above.

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Bacteriological Profile of Chronic Suppurative Otitis Media and its Antibiotic Sensitivity Pattern at a Tertiary Care Hospital

<https://doi.org/10.47210/bjohns.2023.v31i2.976>

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ABSTRACT

Introduction

Aggressive management of chronic suppurative otitis media is necessary as untreated and poorly treated unsafe cases can result in a variety of complications. Aim of this study was to identify the bacteriological profile and determine antibiotic susceptibility pattern of aerobic bacterial isolates in patients of chronic suppurative otitis media.

Materials and Methods

Observational cross-sectional study was conducted at the outpatient department of ENT in collaboration with the department of Microbiology from December 2022 to March 2023. A calculated sample size of 90 ear swabs were taken from 85 cases of chronic suppurative otitis media. Demographic and clinical details were noted. Ear discharges were subjected for aerobic bacterial culture under aseptic conditions along with direct Gram staining. Antibiotic sensitivity testing was done using Kirby-Bauer disc diffusion method on Mueller-Hinton Agar.

Results

Mean age of participants was 33.5 years. 94.1% had the unilateral infection. 94.4% had a tubo-tympanic type while 5.6% had attico-antral type. 70 (77.8%) samples showed mono-microbial growth, 13 (14.4%) showed poly-microbial growth and 7 (7.8%) samples showed no growth in aerobic culture. *Pseudomonas aeruginosa* 38 (39.58%) was the most common organism followed by Methicillin-sensitive *Staphylococcus aureus* 27 (28.13%), Coagulase-negative *Staphylococcus* species 8 (8.33%) and *Klebsiella pneumoniae* 6 (6.25%). *Pseudomonas aeruginosa* was more sensitive to Ciprofloxacin (47.3%), followed by Cefazidime (44.7%), Imipenem (44.7%), Meropenem (42.1%), Gentamycin (42.1%) and Cefepime (42.1%) and was resistant to Ampicillin, Chloramphenicol and Cotrimoxazole. Methicillin sensitive *Staphylococcus aureus* was most sensitive to Vancomycin (100%), Linezolid (100%) followed by Chloramphenicol (96.2), Amikacin (88.9%) and Doxycycline (88.9%).

Conclusion

Antibiotic sensitivity varies at different geographical areas. Continuous and periodic assessment of microbiological patterns and antibiotic sensitivity of isolates is required to formulate local antibiotic policy so that potential risk of complications can be reduced by early initiation of appropriate therapy.

Keywords

Chronic suppurative otitis media; Ear discharge; Bacteriological profile; Antibiotic sensitivity; *Pseudomonas aeruginosa*; *Staphylococcus aureus*

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Active chronic suppurative otitis media is chronic inflammation of the middle ear and mastoid mucosa, with recurrent discharge (at-least 2 weeks) through a chronic perforation of tympanic membrane.¹

Aggressive management is necessary as untreated and poorly treated unsafe chronic suppurative otitis media can result in a variety of complications.² Indiscriminate and inappropriate use of antibiotics to treat chronic

suppurative otitis media has led to the disease chronicity.³ The incidence of chronic suppurative otitis media-related complications has decreased due to the introduction of antibiotics. However, the irrational use of broad-spectrum antibiotics has increased the resistance in the bacteria.⁴ The periodic surveillance for bacteriological profile and its drug sensitivity is thus necessary to plan the general management of chronic suppurative otitis media and it is essential for the ENT surgeon to make the discharging ear dry for better results of myringoplasty and ossiculoplasty.⁵ Culture and sensitivity for antibiotic will help in making a correct choice of antibiotic. The prevalence and antibiogram of these organisms have been reported to vary with time and geographical area along with the advent of newer antibiotics therefore, knowledge of local micro-organism patterns is essential for effective and low-cost treatment.^{6,7} This study is aimed to identify the bacteriological profile and determine antibiotic sensitivity pattern against the aerobic bacterial isolates in patients of chronic suppurative otitis media which can act as a guideline for empirical antibiotic therapy before starting definitive antibiotic therapy.

Materials and Methods

This observational cross-sectional study was conducted at the outpatient department of ENT in collaboration with the department of Microbiology in a tertiary care hospital from December 2022 to March 2023. Ethical clearance for the study was obtained from Institutional Ethical Committee. Written informed consent/assent was obtained from all the patients at the time of enrolment. The sample size was estimated based on the reported bacteriological profile of chronic suppurative otitis media in patients found in previous studies⁸ using the formula $n = 4pq/d^2$ Where, $p = 32.6\%$ (prevalence of *Pseudomonas aeruginosa*), with absolute precision of 10%. Accordingly, the sample size was calculated to be 90 and thus, 90 consecutive ear swab samples were considered for the study.

Patients of all age groups and both genders clinically diagnosed with chronic suppurative otitis media were included in the study. Patients who were on antibiotics or antifungal drugs (topical or systemic) for 7 days or less

before presenting themselves to the OPD, patients diagnosed with any immunodeficiency, patients with malignant lesions of the external and middle ear and patients who had undergone surgery previously in the affected ear were excluded from the study.

Demographic and clinical characteristics of the patients were recorded and noted as per the structured pro-forma. The external auditory canal was cleansed with a sterile cotton pledget soaked in 70% ethyl alcohol. This was allowed to dry. Then using a sterile auditory speculum, a sterile cotton swab stick was introduced into the middle ear for collecting the ear discharge without touching the external auditory canal. Two such samples were collected from each ear and were immediately transported to the Microbiology laboratory. One swab was subjected to Gram staining followed by Microscopy. Another swab was inoculated onto blood agar, chocolate agar and Mac-Conkey agar for aerobic culture and the inoculated plates were incubated at 37°C for 24–48 hours. Blood agar and Mac-Conkey's agar were incubated in aerobic bacteriological incubator for Oxygen requirement, and chocolate agar was incubated in aerobic bacteriological incubator providing 10% CO₂ helping capnophilic organisms to grow at 37 degree celcius for 24 to 48 hours. Cefoxitin discs were used as a surrogate marker for detecting Methicillin Resistant Staphylococcal species. Microbes were identified by gram stain findings under microscope, colony morphology, cultural characteristics and biochemical reactions according to standard bacteriological techniques. Organisms that failed to grow within 48 hours were critically analyzed before excluding as no growth or anaerobic isolate or slow-growing bacteria not routinely reported or slow-growing fungi or due to residual effects of previously treated antibiotics. Antimicrobial sensitivity testing for aerobic bacterial isolates was determined by Kirby–Bauer disc diffusion method on Muller Hinton agar to the panel of antibiotics under Gram-positive cocci/ Gram-negative bacilli/ *Pseudomonas aeruginosa* or non-fermenting group of Gram-negative bacilli according to latest Clinical and Laboratory Standards Institute, M 100, 2022 guidelines.⁹ The data was compiled and statistically analyzed to present the results in the form of numbers and percentages using MS-Excel.

Results

In our study, 85 patients were enrolled making a total sample of 90 ear swabs. The majority of cases were between the age of 16-30 years (32.9%). The mean age of participants was 33.5 years and males were predominantly affected (57.7%). Unilateral infection (94.1%) was more common compared to bilateral infection (5.9%). 94.4% had the tubo-tympanic type of chronic suppurative otitis media while 5.6 had the attico-antral type. (Table I)

Table I: Profile of the study participants

VARIABLE		n (%)
Gender (n = 85)	Male	49 (57.7)
	Female	36 (42.3)
Age in years (n = 85)	< 15	10 (11.8)
	16 – 30	28 (32.9)
	31 – 45	22 (25.9)
	46 – 60	15 (17.6)
	61 – 75	9 (10.6)
	>75	1 (1.2)
Laterality/ side (n = 85)	Unilateral	80 (94.1)
	Bilateral	5 (5.9)
Type of CSOM (n = 90)	Tubo-tympanic	85 (94.4)
	Attico-antral	5 (5.6)

Table II: Microbiological profile of culture growth

TYPE OF GROWTH	n = 90 n (%)
Mono-microbial	70 (77.8%)
Poly-microbial	13 (14.4%)
No growth	7 (7.8)
Total	90 (100)

Out of 90 samples, 70 (77.8%) showed mono-microbial growth, 13 (14.4%) showed poly-microbial growth and 7 (7.8%) samples did-not show any growth in aerobic culture. (Table II)

Table III: Organisms isolated from aerobic culture

TYPE OF BACTERIA	BACTERIAL ISOLATES	n* = 96 n (%)
Gram Negative Bacteria	<i>Pseudomonas aeruginosa</i>	38 (39.58)
	<i>Klebsiella pneumoniae</i>	6 (6.25)
	<i>Escherchia coli</i>	4 (4.17)
	<i>Acinetobacter boumannii</i>	3 (3.13)
	<i>Proteus mirabilis</i>	3 (3.13)
Gram Positive Bacteria	Methicillin sensitive <i>Staphylococcus aureus</i>	27 (28.13)
	Coagulase-negative <i>Staphylococcus</i> species	8 (8.33)
	Methicillin resistant <i>Staphylococcus aureus</i>	4 (4.17)
	<i>Streptococcus pneumoniae</i>	3 (3.13)
*n = 96 (includes micro-organisms from mono-microbial & poly-microbial culture growth)		

Gram-negative bacteria 54 (56.25%) were more frequently observed than Gram-positive bacteria 42 (43.75%). *Pseudomonas aeruginosa* 38 (39.58%) was the most common organism isolated followed by Methicillin-sensitive *Staphylococcus aureus* 27 (28.13%), Coagulase-negative *Staphylococcus* species 8 (8.33%) and *Klebsiella pneumoniae* 6 (6.25%). Methicillin-resistant *Staphylococcus aureus* was isolated in 4 samples (4.17%). (Table III)

Table IV : Antibiotic sensitivity pattern of gram negative bacteria (n = 54)

ANTIBIOTIC	PSEUDOMONAS AERUGINOSA (n = 38) n (%)	KLEBSIELLA PNEUMONIAE (n = 6) n (%)	ESCHERCHIA COLI (n = 4) n (%)	ACINETOBACTER SP (n = 3) n (%)	PROTEUS MIRABILIS (n = 3) n (%)
Ciprofloxacin	18 (47.3)	2 (33.3)	2 (50)	0 (0)	2 (66.6)
Ceftazidime	17 (44.7)	3 (50)	3 (75)	1 (33.3)	0 (0)
Imipenem	17 (44.7)	4 (66.7)	4 (100)	3 (100)	1 (33.3)
Meropenem	16 (42.1)	4 (66.7)	4 (100)	2 (66.6)	1 (33.3)
Gentamycin	16 (42.1)	2 (33.3)	3 (75)	2 (66.6)	2 (66.6)
Cefepime	16 (42.1)	3 (50)	3 (75)	1 (33.3)	0 (0)
Aztreonam	13 (34.2)	3 (50)	3 (75)	0 (0)	0 (0)
Ofloxacin	6 (15.9)	4 (66.7)	3 (75)	0 (0)	2 (66.6)
Tobramycin	6 (15.9)	3 (50)	3 (75)	2 (66.6)	2 (66.6)
Netilmicin	6 (15.9)	3 (50)	3 (75)	2 (66.6)	2 (66.6)
Piperacillin	5 (13.1)	2 (33.3)	2 (50)	1 (33.3)	3 (100)
Amikacin	3 (7.9)	5 (83.3)	4 (100)	2 (66.6)	3 (100)
Cefoxitin	3 (7.9)	2 (33.3)	2 (50)	0 (0)	0 (0)
Cephalexin	3 (7.9)	1 (16.7)	1 (25)	0 (0)	0 (0)
Cefuroxime	3 (7.9)	0 (0)	1 (50)	0 (0)	0 (0)
Ampicillin	0 (0)	0 (0)	1 (25)	0 (0)	0 (0)
Chloramphenicol	0 (0)	1 (16.7)	1 (25)	0 (0)	0 (0)
Cotrimoxazole	0 (0)	2 (33.3)	2 (50)	0 (0)	1 (33.3)

Antibiotic sensitivity patterns of gram-negative and gram-positive bacteria are shown in table IV and V. *Pseudomonas aeruginosa* was more sensitive to Ciprofloxacin (47.3%), followed by Ceftazidime (44.7%), Imipenem (44.7%), Meropenem (42.1%), Gentamycin

(42.1%) and Cefepime (42.1%). *Pseudomonas aeruginosa* was resistant to other commonly used antibiotics like Ampicillin, Chloramphenicol and Cotrimoxazole.

Table V: Antibiotic sensitivity pattern of gram positive bacteria (n = 42)

ANTIBIOTIC	METHICILLIN SENSITIVE STAPHYLOCOCCUS AUREUS (n = 27) n (%)	METHICILLIN RESISTANT STAPHYLOCOCCUS AUREUS (n = 4) n (%)	COAGULASE-NEGATIVE STAPHYLOCOCCUS SPECIES (n = 8) n (%)	STREPTOCOCCUS PNEUMONIA (N = 3) n (%)
Vancomycin	27 (100)	4 (100)	8 (100)	3 (100)
Linezolid	27 (100)	4 (100)	8 (100)	3 (100)
Chloramphenicol	26 (96.2)	1 (25)	8 (100)	3 (100)
Amikacin	24 (88.9)	0 (0)	8 (100)	0 (0)
Doxycycline	24 (88.9)	3 (75)	8 (100)	3 (100)
Amoxicillin-clavulanic acid	23 (85.2)	0 (0)	8 (100)	3 (100)
Cefoxitin	23 (85.2)	0 (0)	6 (75)	-
Erythromycin	23 (85.2)	0 (0)	6 (75)	2 (66.6)
Clindamycin	23 (85.2)	0 (0)	6 (75)	2 (66.6)
Gentamycin	23 (85.2)	0 (0)	8 (100)	0 (0)
Ciprofloxacin	18 (66.6)	2 (50)	7 (87.5)	0 (0)
Cotrimoxazole	18 (66.6)	1 (25)	4 (50)	2 (66.6)
Penicillin	16 (59.25)	0 (0)	0 (0)	3 (100)

Methicillin sensitive *Staphylococcus aureus* was most sensitive to Vancomycin (100%), Linezolid (100%) followed by Chloramphenicol (96.2), Amikacin (88.9%) and Doxycycline (88.9).

Discussion

Chronic suppurative otitis media is a major public health problem and India is one of the countries with a high prevalence rate. It is a disease with a high risk of irreversible complications.¹⁰ It is an important cause of preventable hearing loss particularly in the developing

world and may have long-term effects on early communication, language development, school performance and social interaction.¹¹

In our study, 85 patients were enrolled making a total sample of 90 ear swabs. The majority of cases were between the age of 16-30 years (32.9%). The mean age of participants was 33.5 years and males were predominantly affected (57.7%). Unilateral infection (94.1%) was more common compared to bilateral infection (5.9%). 94.4% had the tubo-tympanic type of chronic suppurative otitis media while 5.6% had the attico-antral type. Similar results were observed by Kombade

SP et al where maximum cases were observed in the age group of 21 to 30 years (25.5%) and males (52.3%) were predominantly affected as compared to females (47.7%). Safe and unsafe type chronic suppurative otitis media was found in 60.1% and 39.9% of cases respectively.¹² In a study conducted by Hiremath B et al, it was observed that the majority of the cases were between the ages of 11-20 years (29.1 %) with male predilection (55.83%). Unilateral infection (77.5%) was more common than bilateral infection (22.5%).¹³ In a study conducted by Shilpa C et al, out of 106 cases studied 63.20% were males and 36.79% were females, giving a male-to-female ratio of 1.6:1. Higher incidence of chronic suppurative otitis media was seen in the age group of 19–45 years (52%).¹⁰

Early microbiological diagnosis assists in prompt and effective therapy to avoid complications. Microbiology cultures yield many organisms and these differ depending on the climate, patient population and usage of antibiotics. In our study of 90 samples, 70 (77.8%) showed mono-microbial growth, 13 (14.4%) showed poly-microbial growth and 7 (7.8%) samples showed no growth in aerobic culture. A total of 9 types of bacteria were isolated (4 gram-positive & 5 gram-negative bacteria). The total number of bacterial isolates obtained was 96 which included all isolates obtained from mono microbial and poly-microbial growth. Gram-negative bacteria 54 (56.25%) were more commonly observed than Gram-positive bacteria 42 (43.75%). Similar observations were made by Kombade SP et al, where bacterial growth was observed in 82.4% of samples while 17.6% showed no growth. Out of pathogenic isolates, mono microbial growth was seen in 90.8% of samples and 9.2% of samples showed poly-microbial growth. Gram-negative bacteria (69.2%) far exceeded Gram-positive bacteria (30.8%).¹² In a study conducted by Shilpa C et al, out of the 106 ear swabs processed, bacterial growth was found in 94.33%, while 5.66% showed no growth.¹⁰ In a study conducted by Hiremath B et al, it was observed that 60.49% of cases were of gram-negative organisms and 39.51% of cases were of gram-positive organisms which shows that gram-negative organisms are more commonly involved in causation of chronic suppurative otitis media.¹³

In our study, Gram-negative bacteria 54 (56.25%) were more commonly observed than Gram-positive bacteria 42 (43.75%). *Pseudomonas aeruginosa* 38 (39.58%) was the more common organism isolated followed by Methicillin-sensitive *Staphylococcus aureus* 27 (28.13%), Coagulase-negative *Staphylococcus* species 8 (8.33%) and *Klebsiella pneumoniae* 6 (6.25%). Methicillin-resistant *Staphylococcus aureus* was isolated in 4 samples (4.17%). The occurrence of *Pseudomonas aeruginosa* as the most common organism could be attributed to the reason that it competitively survives with other pathogens due to its minimum nutritional requirements, its relative resistance to antibiotics, and its armamentarium of antibacterial products—pyocyanin and bacteriocin and its predilection for moist areas.^{10,13} Similar observations are made by Hiremath B et al where *Pseudomonas aeruginosa* (38.79%) was the most commonly isolated aerobic bacteria followed by *staphylococcus aureus* (32.75%) and methicillin-resistant *staphylococcus aureus* (5.17%).¹³ Similarly, Shilpa C et al reported that *Pseudomonas aeruginosa* was the most commonly isolated bacteria (49%), followed by *Staphylococcus aureus* (18%).¹⁰ Similarly observations were made by Wan Draman et al and Kombade SP et al.^{8,12}

Our study revealed that *Pseudomonas aeruginosa* was more sensitive to Ciprofloxacin (47.3%), followed by Ceftazidime (44.7%), Imipenem (44.7%), Meropenem (42.1%), Gentamycin (42.1%) and Cefepime (42.1%). *Pseudomonas aeruginosa* was resistant to other commonly used antibiotics like Ampicillin, Chloramphenicol and Cotrimoxazole. According to study done by Hiremath B et al *Pseudomonas aeruginosa* showed maximum sensitivity to piperacillin (91.11%), followed by gentamicin (71.11%), amikacin (71.11%), moderate sensitivity to ceftazidime (51.11%), and resistant to carbapenem (60%).¹³ In a study done by Rangaiah ST et al it was observed that *Pseudomonas aeruginosa* was more sensitive to Piperacillin (88.09%), Tazobactam (88.09%), Meropenem (80.95%) and Ciprofloxacin (73.8%).³ The lower susceptibility to antibiotics like imipenem and meropenem could be attributed to

inappropriate usage of higher antibiotics at health care setups.

In our study Methicillin sensitive *Staphylococcus aureus* was most sensitive to Vancomycin (100%), Linezolid (100%) followed by Chloramphenicol (96.2), Amikacin (88.9%) and Doxycycline (88.9). According to study done by Hiremath B et al *Staphylococcus aureus* showed maximum sensitivity to erythromycin (71.05%), followed by cotrimoxazole (63.15%), and ampicillin (55.26%). Maximum resistance was observed for ciprofloxacin (78.9%), followed by amoxiclavate (55.26%).¹³In a study done by Rangaiah ST et al it was observed that staphylococcus was more sensitive to linezolid (86.04%), cefoxitine (55.81%) and erythromycin (51.16%).³

These antibiotic sensitivity pattern in different studies reflects that antibiotic sensitivity varies at different geographical areas which highlights the importance of formulating local antibiotic policy so that the potential risk of complications can be reduced by early institution of appropriate treatment

Conclusion

The emergence of antibiotic resistance is becoming more frequent due to the indiscriminate and inappropriate use of antibiotics in this present era of rapid advent of newer antibiotics. Also, the discontinuation of antibiotics by chronic suppurative otitis media patients before completion of the course may allow partially resistant microbes to flourish. Such practice should be discouraged through proper health education. The knowledge regarding the spectrum of microorganisms and their antibiotic susceptibility is important for effective treatment. Our findings reflect the importance of periodic evaluation of microbiological patterns and antibiotic sensitivity of isolates. This helps to formulate local antibiotic policy for the appropriate use of antibiotics in chronic suppurative otitis media so that the potential risk of complications can be decreased by early institution of appropriate treatment. This can act as a guideline for empirical antibiotic therapy

where antibiotic policy is not formulated and for initiating empirical treatment until final antibiotic sensitivity report is available.

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Unusual Benign Middle Ear Tumors

<https://doi.org/10.47210/bjohns.2023.v3i2.928>

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ABSTRACT

Introduction

Middle ear tumors represent a rare group of neoplasm that vary widely according to their pathology, anatomical involvements and clinical features. They mimic middle ear inflammatory pathologies intricately and hence early definitive diagnosis is a challenge. As these tumors are histologically benign, they are only locally destructive causing vestibular/facial dysfunction.

Materials and Methods

In this case series, we have included 5 cases of rare middle ear tumors, who presented to our hospital in period of 2020-2023. All patients had a pre-operative examination with otoscope and microscope/otoendoscope. Pre-operative and post-operative hearing assessment done with tuning fork test and pure tone audiometry. Pre-operative radiological investigation done in all cases. Biopsy was usually taken pre-operatively, however in tumors suspected to be highly vascular an intra-operative sample was sent.

Results

Mastoidectomy (canal wall up/canal wall down/radical) was performed as definite surgical treatment to achieve maximum clearance.

Conclusion

Surgery is the treatment of choice for benign middle ear tumors. High resolution computed tomography and magnetic resonance imaging are important to determine the extent and to help surgical planning in doubtful vascular tumour. Biopsy is helpful for the differential diagnosis.

Keywords

Benign; Ear Polyp; Mastoidectomy; Histopathology

Benign tumors arising from the middle ear contribute a very small fraction of all ear pathologies. Being a heterogeneous group, their presentation varies; though most mimic Chronic Suppurative Otitis Media intricately. Swift establishment of clinicopathological diagnosis is a challenge. As these lesions are benign, they are locally destructive; hence leading to audiological and facial/vestibular dysfunction. Early diagnosis is necessary to prevent these associated complications.

They are classified into two groups:

1. Primary tumour of the middle ear

2. Tumors of adjacent structures that involve the middle ear spaces.

Most common primary tumors are paraganglioma (glomus tumour), followed by adenoma in adults and by haemangiomas in children. Primary tumors may extend from the middle ear space intracranially or into the other portion of the temporal bone and skull base.¹ High resolution Computed tomography (HRCT) and magnetic resonance imaging (MRI) are useful in defining the extent and nature of the lesion.² While microscopic or otoendoscopic examination is always done preoperatively in all polyp/mass in the ear cases, biopsy is must for definitive diagnosis. It may sometimes be difficult to distinguish between polyps arising from the middle ear and those arising from the external ear since both may fill the meatus and obscure the exact site of origin. So far, the surgical intervention has been the mainstay of

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treatment. Surgical excision with radical extent is definitive to achieve maximum clearance.

The aim of this study is to present five cases of these relatively rare disease in the middle ear, discuss the clinical characteristics of the disease, and to highlight the management. In this case series we have included five rare and anatomically complex tumors. We have also discussed their optimal surgical management to achieve optimal clearance and to prevent recurrence.

Materials and Methods

Cases of middle ear tumors reported on histopathology pre-operatively and/or intra-operatively were enrolled. Pre-operatively otoscopic and otoendoscopic/microscopic examinations were done in all cases. Origin and anatomical location of the tumour was detailed. Biopsy was taken under otomicroscopy with adequate preparation for haemostasis. We have analysed the clinical characteristics of these five cases after ruling out chronic otitis media; such as gender, age, clinical manifestations, clinical images, radiological correlation, intraoperative extension, intraoperative clearance of the disease, pathological data, surgical approach. Audiological investigation done preoperatively and postoperatively (after 3 months) with pure tone audiogram and tuning fork test. All data were documented.

Case series:

Case 1

Glomus tympanic Paraganglioma : A 32-years old female presented with complaint of blood stain right ear discharge with earache for 6 months. On otoscopic examination mass was seen arising from tympanic membrane. Clinically we were suspecting vascular mass, so biopsy was not taken pre-operatively. Pure tone audiogram suggested severe conductive hearing loss. MRI was suggestive of presence of poorly defined abnormal signal intensity mass lesion involving middle ear extending up to external auditory canal, eustachian tube and mastoid air cell, reaching up to tegmen tympani. Right radical mastoidectomy done. Intra operatively tumour

extending up to antrum, aditus, external auditory canal (EAC), sinus plate, dural plate, part of eustachian tube and carotid area, lenticular process of incus necrosed, stapes partially eroded and preserved. No major complications were seen. Post-operative histopathology report suggested of glomus tympanic tumour. She is disease free till this time.

Case 2

Capillary haemangioma : A 43-year-old female presented with left-sided hearing loss with ear discharge for 1 year. On otoscopic examination a bright red polypoidal mass occupied the whole of external auditory canal, occluding the view of tympanic membrane. It seemed like vascular tumour during examination, so biopsy was not taken pre operatively. Pure tone audiogram revealed moderate conductive hearing loss. HRCT was suggestive of ill defined, non-enhancing hyper-intensity involving left external auditory canal, left middle ear cavity and mastoid air cell. Intraoperatively, the tumour was found to occupy the entire epitympanum and mesotympanum. The mass had encased the entire ossicular chain without any erosion. The incus and malleus were removed to facilitate tumour excision. Canal wall down mastoidectomy with type 3 tympanoplasty done. Total clearance could be achieved. Biopsy confirmed the clinical suspicion of capillary haemangioma. No major post-operative complication seen and the cavity healed uneventfully in 4 weeks.

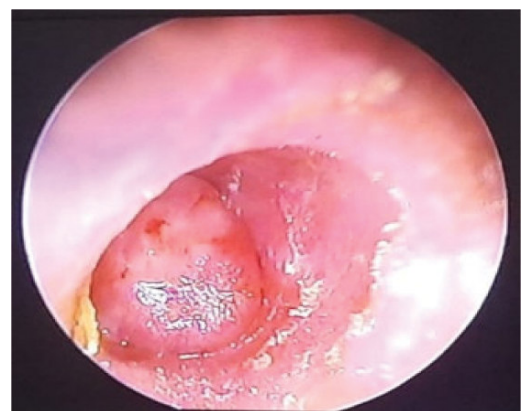


Fig. 1. Oto-endoscopic examination showed tumour arising from posterosuperior region of left ear

Case 3

Myxoma: A 45-year-old female presented with Left otalgia and ear discharge for six months. Oto-endoscopic examination revealed a polypoidal tissue in postero superior quadrant (PSQ) region coming from middle ear. A small bit was sampled and biopsy suggested myxoma. Audiogram suggested of moderate conductive hearing loss. HRCT of the temporal bone revealed, left mastoid air cell markedly filled with tumour. Mastoid antrum, air cell and tympanic cavity were filled with hypodense tissues. Post-operative histopathology showed marked proliferation of spindle to stellate shaped cells deposited in extensive myxoid stroma, suggestive of myxoma. Canal wall up mastoidectomy with type 1 tympanoplasty was done as no ossicular erosion was noticed. No major post-operative complication seen.

Case 4

Facial Schwannoma: A 62-year-old female came with complains of severe left ear pain and ear discharge. On Microscopic examination, polypoidal tissue was present in EAC coming from PSQ region. Pure tone audiogram

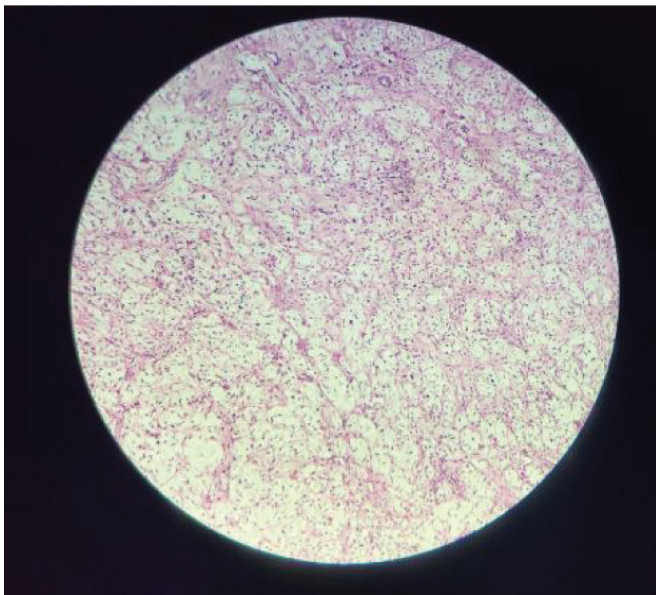


Fig. 2. Post operative Histopathological examination (hematoxylin and eosin stain under 40x magnification) suggested of schwannoma

suggested of profound mixed hearing loss. HRCT temporal bone revealed ill-defined tissue density lesion is seen in the external auditory canal, mesotympanum and hypotympanum. Intraoperatively the tumour found to be arising from second genu of facial nerve and was in close proximity to chorda-tympani nerve. Tumour could be peeled off facial involving the epineurium, however the segment of chorda in contact with lesion was sacrificed. It involved mesotympanum, hypotympanum, sinus tympani. Tumour was removed in-toto and canal wall down mastoidectomy with type 3 tympanoplasty reconstruction was done. Post-operative histopathology report suggested of schwannoma. As even post-operative no facial palsy was seen, we inferred it to be Chordal Schwannoma.

Case 5

Myxoma in childhood: A 7 years male child with complaint of swelling over left side pre and post aural swelling for 3 years. Swelling was small in size, gradually progressive. It was associated with decreased hearing; although no vertigo, nystagmus or facial palsy was present. On otoscopic examination, a polypoidal mass in the external ear canal that was covering whole of the canal and further not negotiated to see the tympanic membrane. History of twice excision biopsy from swelling done 1.5 year and 1 year back at some peripheral hospital. Histopathology report was suggestive of low grade myxoid tumour. Patient visited to us with swelling over pre and post auricular region with discharge coming from it. Audiometry suggested mild conductive hearing loss. HRCT temporal bone showed abnormal fluid density noted in left external auditory canal, middle ear cavity and mastoid air cells with abutting left parotid gland with effaced fat plane, thinning of tegmen tympani was noted. MRI showed multi-lobulated abnormal signal intensity lesion, in left mastoid air cells and middle ear extending into left external auditory canal and in left infra mastoid region; lesion was causing superior bulging and scalloping of tegmen tympani without invasion of adjacent brain. It

measures approximately 7.0 (CC) x 5.0 (W) x 4.3 (AP) cm in size. It is displacing parotid gland infero-medially without invasion. As this tumour involved preauricular area, we kept extended modified Blair's incision. Intra operatively tumour was going into zygomatic area anteriorly, parotid gland was displaced inferomedial and middle ear superiorly. Tumour separated from surrounding tissues, removed. Mastoid bone was exposed through the same incision. On drilling the mastoid bone tumour was reaching and completely filling air cell system, without significant bone destruction. Epitympanum, Mesotympanum and Hypotympanum was also completely engulfed with tumour tissue. Eustachian tube was identified and blocked with muscles tissue. Closure over preauricular region was done with rotation of temporalis muscle. Facial functions were all preserved after surgery. Post-operative histopathological report was suggestive of hyperplastic squamous epithelium, myxoid stroma with scattered spindle and stellate shaped cells suggestive of low grade myxoid tumour.



Fig. 3. Pre operative, intraoperative tumour location with closure

Table I : Summary of five cases

SR. NO.	AGE/ SEX	CASES	PRE OP HPR	POST OP HPR	SURGERY REQUIRED
1.	32/F	Glomus tympanic paraganglioma	Not done	Glomus tympanic	Radical mastoidectomy
2.	45/F	Capillary haemangioma	Not done	Capillary haemangioma	CWD mastoidectomy type3 tympanoplasty
3.	42/F	Myxoma (female)	Myxoma	Myxoma	CWU mastoidectomy type 1 tympanoplasty
4.	65/F	Schwannoma	Polyp	Schwannoma (chordal)	CWD mastoidectomy type 3 tympanoplasty
5.	07/M	Myxoma (childhood)	myxoma	myxoma	Radical mastoidectomy

(op = operative, HPR = histopathology report, CWD = canal wall down, CWU = canal wall up)

Discussion

Middle ear tumors are rare and are best evaluated with imaging studies. As they imitate otitis media, High resolution Computed Tomography imaging is the key their assessment. When combined with patient's clinical findings, Computed Tomography findings can assist in disease classification which is helpful for definitive surgery. Surgical excision with histopathologic analysis is usually required for definitive diagnosis and treatment. They are classified into two groups: 1. Primary tumour of the middle ear and 2. Tumors of adjacent structures that involve the middle ear spaces. Most common primary tumors are paraganglioma (glomus tumour), followed by adenoma in adults and by haemangiomas in children.

The paraganglioma are also known as glomus tumour or chemodectomas. Incidence of paraganglioma tumour said to be about one per 1.4 million people per year. These are frequently seen in women (66-90%) in 4th and 7th decades of life. It can cause hearing loss, tinnitus, dizziness, facial palsy. Paragangliomas can be divide into three categories: 1) Jugular paragangliomas 2) Tympanicum paragangliomas 3) Jugulo-tympanicum paraganglioma. MRI helps in recognizing the characteristic vascularity of the tumor.³ Histopathologically, epitheloid or spindle-shaped cells are seen to form nests or layers, and stroma has a rich vascular network. The tumour resection is usually done via trans mastoid approach and almost universally converted into canal wall down mastoidectomy in the view of the size of the tumour.

Capillary haemangioma is classified as a vascular tumour, while cavernous lesions are vascular malformations.⁷ Vascular anomalies are common in head and neck but rarely reported in the ear. Only 18 cases have been reported in English literature and out of which, only one with hemangioma of middle ear was extended to the mastoid cavity. Haemangiomas are tumors growing with age. They can cause significant morbidity in the enclosed spaces of the ear. Clinically usually reddish polypoidal mass is seen in EAC occluding further visualization. Imaging is indicated to classify and assess the extent of the lesion. Bony structures are usually intact, however erosion of EAC, ossicles and facial canal may

be seen in some cases due to pressure effect. Their management depends on the diagnosis and its presentation. Radical Surgery with complete excision is the treatment of choice.⁸

Schwannomas are generally seen over the age of 40 years. But Age of presentation varies from 5 to 84 years. No gender or side predilection is observed.⁴ It is mostly seen unilateral. It is seen bilaterally in the syndrome of neurofibromatosis type 2. One study of 600 cadaver temporal bone studies reported facial Nerve Schwannoma incidence of 0.8%. The incidence of infratemporal facial neuromas was 0.8% in a cadaveric study, although this figure is higher than the rate of clinical presentation.⁵ They are generally encapsulated well-circumscribed lesions. As in schwannomas seen elsewhere, it consists of Antoni A fields and Verocay bodies. Hyalinized vessel walls are encountered. Degenerative changes such as haemorrhage, necrosis, and myxoid changes can be observed. Diagnostic workup includes audiometry (audiological test), auditory brain stem evoked response audiometry, Computed Tomography, and contrast-enhanced MRI. Treatment includes surgical removal. Approach depends on the site of tumour, size of tumour, and hearing loss. Timing for surgery is controversial because facial nerve neuromas almost always grow slowly.⁶

Myxoma is the benign tumour originating from the mesenchymal tissue. It is rare tumour and its molecular mechanism and prognosis remain unclear till date. Myxomas in the head and neck areas are most commonly seen in maxilla and mandible. Myxoma is very rare benign tumour of the middle ear. However, it may also develop in the auricular, ear canal, middle ear and temporal bone. Only 5 cases of isolated myxoma of the external auditory canal have been reported in the literature.⁹ The typical myxoma develops from the atrium of the heart. It is mostly seen as carney complex. Carney complex is a hereditary condition associated with spotty skin pigmentation with connective tissue tumors; and a number of other tumours of the endocrine (hormone-producing) glands. Carney complex is inherited autosomal dominantly and PRKAR1A gene mutations or deletions are seen in

patients. Management is mainly complete surgical resection.

Traditional trans canal approaches should be reserved for small, discrete masses in the mesotympanum. A postauricular incision is more appropriate for excising small, discrete lesions of the anterior mesotympanum or when mastoidectomy is anticipated for tumors that extend to the epitympanum, hypotympanum, or outside the middle ear space. When the tumour invades the pre-auricular/parotid space an extended parotid-neck incision can also serve as approach for mastoidectomy with maximal

retraction. In all cases hearing outcome was noted. Preoperative and postoperative audiological assessment done with Tuning fork test (table II) and Pure tone audiometry. For tumors that involve the mastoid cavity, canal wall-up mastoidectomy is preferred in uncomplicated resections. However, there should be little hesitation to convert it to a canal-wall-down procedure to achieve better exposure and haemostasis. Finally, a complete and safe resection of a middle ear tumour often requires disarticulating the ossicular chain, and surgeons should have a low threshold for doing so.¹⁰

Table II : Pre operative and post operative hearing assessment with Tuning fork test

TUNING FORK	CASES	RINNE NEGATIVE		RINNE POSITIVE		WEBERS LATERALISED TO AFFECTED EAR		WEBERS LATERALISED TO OPPOSITE EAR		ABSOLUTE BONE CONDUCTION TEST (NOT DECREASED)		ABSOLUTE BONE CONDUCTION TEST (DECREASED)	
		Pre op	Post op	Pre op	Post op	Pre op	Post op	Pre op	Post op	Pre op	Post op	Pre op	Post op
256 Hz		2	0	1	2	2	2	1	2	2	0	1	0
516 Hz		4	3	1	2	4	2	1	2	4	3	1	0
1024 Hz		4	3	1	2	4	2	1	2	4	3	1	0

Conclusion

Benign middle ear tumors should be differentiated from chronic otitis media as management protocols differs. Otomicroscopic examination and biopsy are ideal though should be reserved for clinico-radiological non-vascular tumour. High resolution computed tomography and magnetic resonance imaging are important to determine the extent and to help surgical planning in doubtful vascular tumour. It is also important for the differential diagnosis. Surgery (modified radical mastoidectomy/radical mastoidectomy) with hearing reconstruction is the treatment of the choice for benign middle ear tumors. Even though the tumour can be successfully treated with surgical resection and long term follow up is required to assess recurrence.

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Giant Ectopic Minor Salivary Gland Tumour in Parapharyngeal Space

<https://doi.org/10.47210/bjohns.2023.v31i2.791>

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ABSTRACT

Introduction

Parapharyngeal tumours are rare head neck masses (0.5%). Most of them are benign. Deep location of this space and surrounding structures has led to emergence of many different approaches to this space reflecting the intrinsic difficulty in surgical access.

Case Report

An ectopic minor salivary pleomorphic adenoma of parapharyngeal space with massive extension.

Discussion

Parapharyngeal space has complex anatomy, its deep location and relationship with vital structures renders a surgical challenge. Clinical examination of the space is difficult, so imaging plays a major role to know its origin and extension. Pleomorphic adenoma is the most common tumour from the extension of deep lobe of Parotid gland but very rarely from the ectopic minor salivary glands. Excision of benign parapharyngeal space tumours is possible without mandibulotomy even in the case of a large tumour mass reducing patient morbidity and hospital stay.

Keywords

Parapharyngeal Space; Pleomorphic Adenoma; Minor Salivary Gland

The parapharyngeal space (PPS) is an inverted pyramidal shaped deep neck space extending from the skull base to the hyoid bone. It can be divided into two compartments: prestyloid or anterolateral and post-styloid (posteromedial) separated by the tensor veli palatini muscle and the styloid process.

Tumours of the parapharyngeal space are rare and comprise less than 1 % of all head and neck neoplasms.¹ Majority of PPS are benign (70–80%); approximately half of them originating from the salivary glands (40–50%), while the rest arise from nerve structures (20%) or are enlarged lymph nodes (15%). Approximately, 20% are malignant. Pleomorphic adenoma is the most common out of all PPS tumours.² Different surgical approaches have been described for PPS tumours. The transcervical approach was first described by Morfit³ while the

transcervical trans parotid approach is the most widely used; the trans palatal or transoral approaches are associated with less morbidity, but are limited to small lesions if used alone.

Case Report

In the ENT out patient department a 44-year-old female presented with a painless swelling on the right side of neck in the infra-auricular region for 7 years. It was

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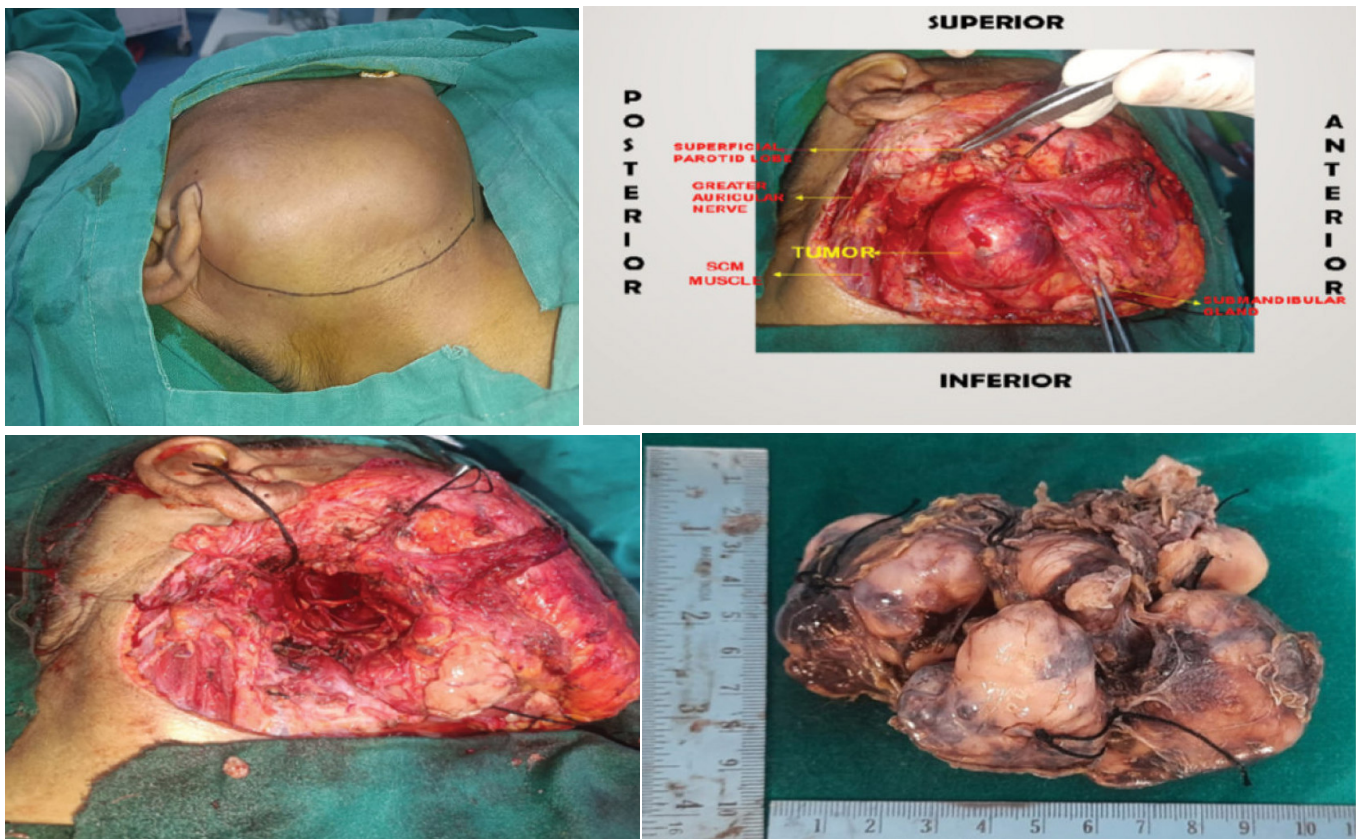


Fig. 1. Intra operative pictures

insidious in onset, gradually progressive. Voice change for 2 years. There was no history of difficulty in breathing or swallowing. Inspection- About 6 x 4 x 3 cm lobulated swelling seen in the right parotid region extending postero-superiorly behind the lobule up to the mastoid tip, posteriorly lying over the anterior border of SCM muscle, in infra-auricular region extending anteromedially in the neck below the angle of mandible up to submandibular region, overlying skin was normal but stretched, no discoloration or scar seen. On palpation a single large lobulated swelling with smooth surface, normal skin temperature, non-mobile, non-reducible, firm to hard, fixed to underlying structures, overlying skin free. There was no bruit on auscultation. Intra orally a mass was seen bulging behind the right anterior pillar pushing the soft palate and uvula from midline to the left. (Figure 1)

CECT neck showed - 5 x 10 x 7 cm well defined lobulated heterogeneously enhancing soft tissue lesion in right infratemporal fossa, displaces deep lobe of parotid laterally. Antero inferiorly causes widening of mandibular canal, thinning and lateral bulge of vertical ramus of mandible. Rt TMJ subluxation. Anteriorly widening and remodelling of pterygoid plates. Carotid space displaced postero laterally, lesion compresses right IJV. Inferiorly indents right submandibular gland. Differential diagnosis were benign neoplasm, paraganglioma, mandibular nerve sheath tumour. USG abdomen and pelvis was done to rule out any adrenal tumour (phaeochromocytoma) or lymphoma. FNAC was suggestive of pleomorphic adenoma. MRI face & neck- Multilobulated heterogenous signal intensity space occupying lesion of approx. 5 x 10 x 7 cm (ap x tr x cc) in right PPS with extension into

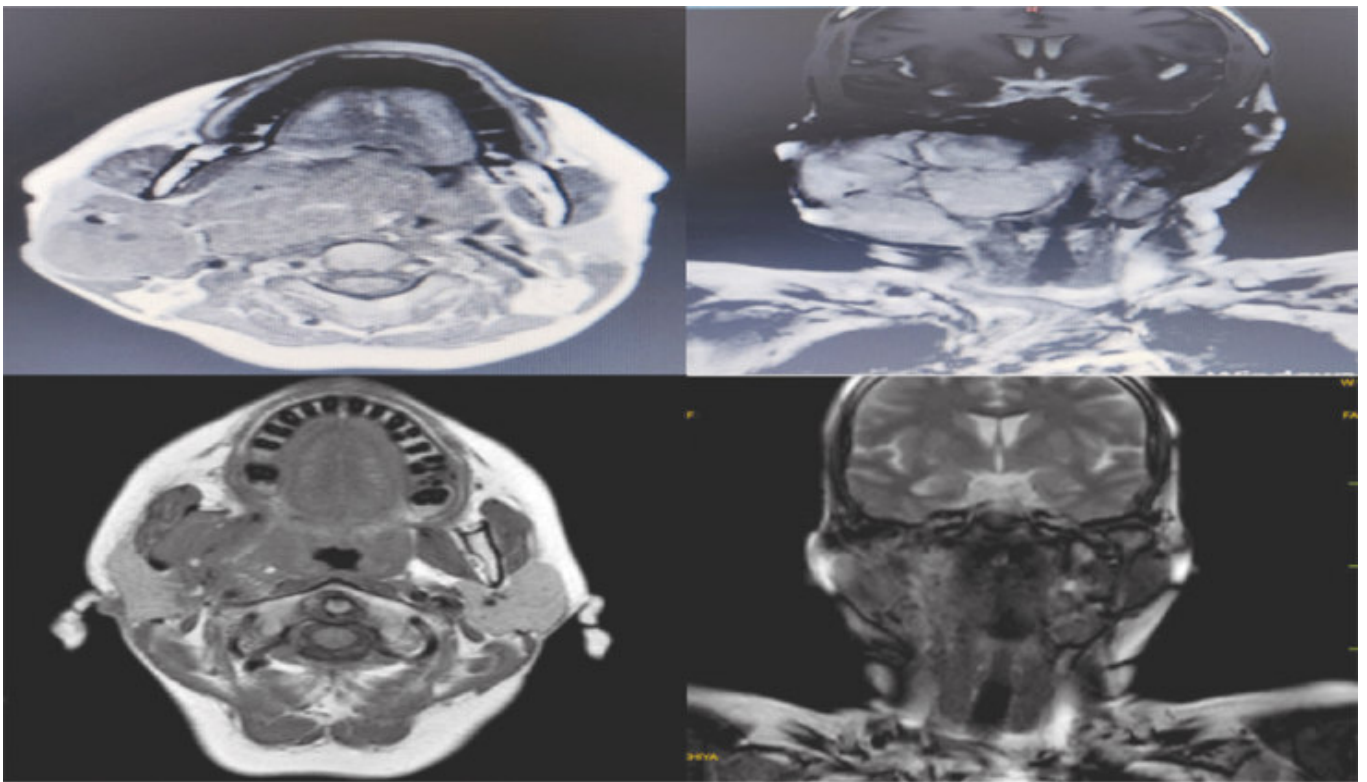


Fig. 2. MRI with contrast (T2W) axial and coronal sections A, B- Preoperative C, D- Postoperative

masticator space, compromised oropharyngeal lumen due to mass effect, extending into submandibular space compressing right submandibular gland. Significant compression of deep lobe of parotid postero-laterally was seen. Carotid and jugular was displaced posteriorly suggestive of neoplastic mass in right parapharyngeal space. (Figure 2)

Transcervical trans parotid excision of the mass was done in total. Modified Blair incision was combined with transcervical incision. Subplatysmal flaps were elevated and tumour was exposed. A multilobulated tumour was seen pushing the superficial parotid lobe laterally, branches of facial nerve seen stretched over the tumour, preserved one lobe going deep in ITF. Submandibular gland was pushed antero inferiorly. The superior extent was up to foramen ovale causing its widening. Tumour was separated from surroundings including styloid apparatus, deep lobe of parotid and submandibular gland by blunt dissection, deep lobe of tumour was seen going

into infratemporal fossa. No nerve involvement seen. The excised mass was sent for histopathological examination. Patient developed slight deviated angle of mouth (marginal mandibular nerve stretching), rest cranial nerve functions were preserved. Diagnosis on histopathological examination confirmed pleomorphic adenoma of minor salivary gland.

Discussion

The PPS has a complex anatomy, its deep location and relationship with the vital structures renders a surgical challenge. It is anatomically divided into two compartments: pre- and post-styloid.⁴ The pre-styloid compartment mainly contains deep lobe of the parotid gland, minor salivary glands, the internal maxillary artery, and branches of the mandibular branch of the trigeminal nerve, while the retro-styloid compartment contains the internal carotid artery, internal jugular vein, cranial nerves

IX to XII, cervical sympathetic chain, fat and lymph nodes.⁵ Clinical examination of the PPS is difficult; so imaging studies are critical for evaluation of PPS tumour. They usually remain undetected for a long time because of their location. Usually presents as an asymptomatic neck mass or oropharyngeal mass. Prestyloid PPS tumour produces otitis media, hoarseness, nasal obstruction, dysphagia or dyspnoea; those from the post-styloid compartment may present as speech difficulty, dysphagia, dysarthria or Horner's syndrome due to compression of cranial nerves IX, X, XI and XII.⁸ Cranial nerve palsy, pain or trismus is suggestive of malignancy.⁶

A contrast CT, as well as an MRI, and angiography in selected cases, are vital for diagnosis and for planning the therapeutic approach.⁸ Pre-operative FNAB use is debatable because of its poor sensitivity in confirming the final histopathologic diagnosis.⁴ The surgical approach to this space is controversial,⁷ with the transcervical-trans parotid approach being the most widely used worldwide; however, other surgical approaches have been described such as transoral, transcervical submandibular, modified transcervical (transcervical-trans mastoid, transcervical with mandibulotomy), trans mandibular and lateral approaches to the skull base.⁸ In the case of a large PPS mass, mandibular osteotomy has been advocated for a better exposure of important neurovascular structures in the carotid space. The side effects of mandibulotomies have been a facial scar caused by lip splitting, difficulty in mandibular healing, malocclusion, loss of mental nerve sensation and paralysis of the mandibular branch of the facial nerve. Therefore, avoiding mandibulotomy reduces patient morbidity and hospital stay; food intake can start on the first post-operative day, a better cosmetic result without lip splitting is obtained and tracheotomy is usually not necessary; operating time is also reduced with transcervical or transcervical-trans parotid approach.

Conclusion

In conclusion, PPS tumours are rare and the majority of them are benign. Pleomorphic adenoma of minor salivary gland which itself is a very rare in occurrence can be

seen in ectopic site like PPS and they can present as a huge parapharyngeal tumour. So, although rare but it is a considerable differential diagnosis. As the majority of neoplasms encountered in the PPS are benign, it is essential that any surgical procedure in the PPS be designed to minimize morbidity and mortality. We believe that with the modification of transcervical incision huge tumours as big as 11 x 11 cm (as in our case) can be successfully removed without any significant comorbidities.

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A Case Report on Kimura Disease

<https://doi.org/10.47210/bjohns.2023.v31i2.932>

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ABSTRACT

Introduction

Kimura disease is a rare chronic inflammatory disease that, if occurs in the head and neck region, presents with a swelling.

Case Report

A 14-year-old male presented to our ENT OPD with a painless left cheek swelling. The swelling was first noticed by the patient about 3.5 years back. The swelling was gradually progressive in size. It was mobile in all directions, cystic in consistency and non-tender.

Discussion

Kimura Disease is a rare chronic inflammatory disorder described as a "eosinophilic hyperplastic lymphogranuloma" in Chinese literature. This disease is endemic in middle-aged Asian males and is seen sporadically in the non-Asian population. There is no standardized treatment protocol present for Kimura Disease. Treatment modalities include surgical resection, cytotoxic and radiation therapy, as well as regional or systemic steroid therapy. The role of surgery is primarily for diagnostic and cosmetic purposes. Relapses are common and recurrence rate is high. The overall outcome is good as there is no association with malignancy.

Keywords

Kimura Disease; Chronic Inflammatory Disorder; Head and Neck; Steroid

Kimura disease (KD) is a rare chronic inflammatory disorder that usually presents as a subcutaneous swelling in the head and neck region, associated with lymphadenopathy. It may also involve the salivary glands. It is a benign disorder, first reported by Kimm and Szeto in 1937 in China.¹ In 1948, a Japanese doctor named Kimura described the details of the disease and coined the term 'Kimura Disease'.² KD is rare in India and only 200 cases have been reported worldwide as its diagnosis is mainly based on the histopathological features.³ It is generally seen in young Asian adults,⁴ with the maximum prevalence being in the 20-40 year age group. Males are affected more than women.^{5,6} The disease apart from being endemic in Asian countries, occurs sporadically in other places also. Patients usually present with a mass in the head and neck region with involvement of subcutaneous soft tissue, salivary glands, and occasional regional lymphadenopathy.^{7,8} Peripheral blood smear shows persistent eosinophilia and increased serum IgE levels. These two features appear to be

consistent with KD. The disease is self-limiting, although recurrences can occur over a period of years. The disease may be commonly associated with renal disease.⁹ The diagnosis is often difficult, and biopsy or excision of the involved mass for a pathological study is necessary. Here we report a rare case of a 14 year old male with a left cheek mass.

Case Report

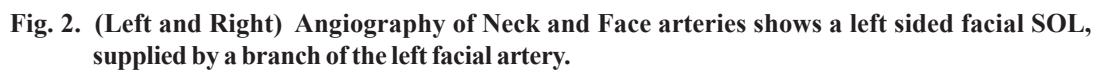
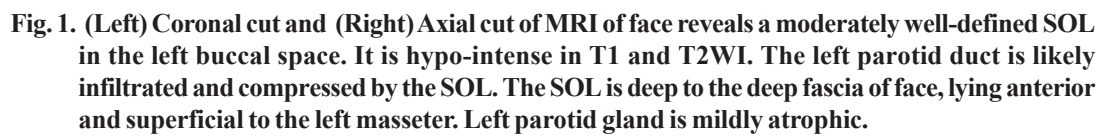
A 14 year old male presented to our ENT OPD with a painless left cheek swelling which was about 4*5 cm in dimension. The swelling was first noticed by the patient about 3.5 years back. The swelling had slowly increased in size since then. The patient visited multiple doctors

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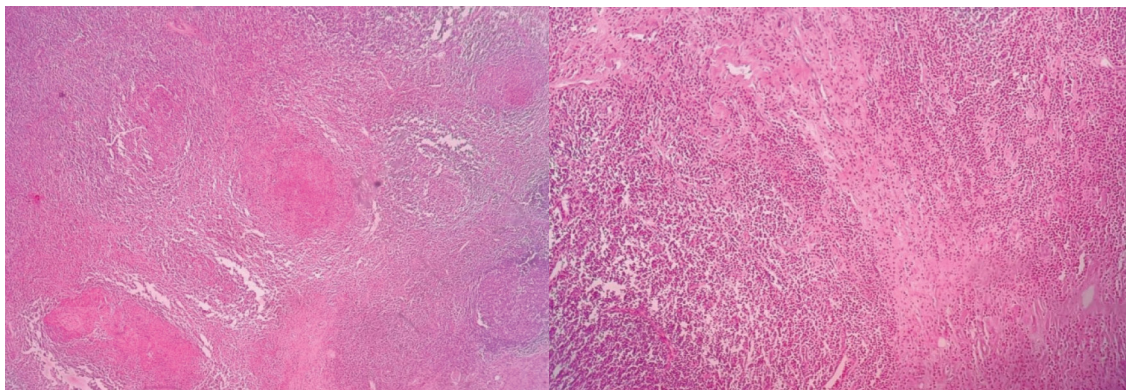


Fig 3: (Left) 40x magnification(H&E stain) and (Right)100x magnification (H&E stain). Images show multiple lymphoid follicles with prominent germinal centres, along with multiple proliferating blood vessels. In between the lymphoid follicles a large number of eosinophils are present.

and health facilities but did not get any symptomatic relief even after various treatments. On examination, the swelling was mobile in all directions, cystic in consistency and non-tender. Skin above the swelling appeared normal. Oral cavity examination revealed a grade 3 tonsillar hypertrophy but other findings were normal.

There was also a 2 cm swelling present in the left preauricular region which was mobile, non-tender and firm in consistency. There was no history of low-grade fever, cough or any chronic symptoms. Few level 2 lymph nodes on the left side of neck were palpable. No other regional lymphadenopathy was seen or felt. Systemic examination was normal.

His blood examination revealed white blood cell count to be 12100/microlitre. The percentage of eosinophil was about 19.5%, normal being in the 2-4% range.

Ultra sound examination showed a 34*25 mm echoic cystic swelling with stippled calcification along with increased internal vascularity.

Ultra sound of the kidney-ureter-bladder region was normal.

MRI neck suggested a well-defined altered intensity heterogeneous soft tissue mass lesion in the left buccal fat pad. Mild atrophy of the left parotid gland, possibly due to infiltration of the duct, was noted. Bilateral level 2 lymph nodes and left sided level 1b lymph nodes were enlarged. (Fig. 1)

Angiogram of neck arteries suggested that the lesion was being fed by a branch of the facial artery. (Fig. 2)

After obtaining fitness for surgery, the left cheek mass was excised via lateral rhinotomy approach. The specimen was sent for Histopathological examination. Suture removal was done on post operative day 7. Post operative period was uneventful.

Excisional biopsy from left cheek lesion revealed a polymorphous population of lymphoid cells comprising predominantly of mature lymphocytes mixed with germinal centre cells, plasma cells, histiocytes and a few tangible body macrophages (Fig. 3).

After histopathological study suggested that it was KD, we started him on oral prednisolone. After the local swelling of the cheek was excised, the post auricular swelling reduced rapidly. There was a decrease in size of the faucial tonsil also. After a few days of observation in the ward, we discharged him with oral corticosteroids.

Discussion

KD is a rare chronic inflammatory disorder. In 1937, Kim and Szeto first described the disease as “eosinophilic hyperplastic lymphogranuloma”.¹⁰ The disease is known to us as KD since its detailed description can be found in a paper by Kimura et al. published in 1948.¹¹ This disease is endemic in middle-aged Asian males and seen

sporadically in the non-asian population. Chen et al. concluded in their study that KD should be included in the differential diagnosis of any lymph node demonstrating an eosinophilic infiltrate and prominent follicular hyperplasia, in a patient of any race.¹² The disease is mainly seen in males within the 2nd and 3rd decade, but can be found at any age.⁴ It presents predominantly as subcutaneous nodules in the head and neck, often unilateral, and frequently associated with lymphadenopathy. Salivary glands can also be involved in the disease. Orbit, eyelid, palate, axilla, groin, and arm and pharynx have also been reported to be involved.^{12,13} The disease is generally benign and self-limiting. Although it is a chronic inflammatory disorder with unknown etiology and pathogenesis, the presence of eosinophilia and increased serum levels of IgE, mast cells, IL-4, IL-5 and IL-13 in patients suggests either an unusual autoimmune response or an immune reaction towards an allergen.¹⁴ Clonal T-cell population contributes to the disease development and recurrence.¹⁵ Although there is no specific diagnostic feature of KD, fine needle aspiration cytology is helpful in the preoperative diagnosis.

Hui et al. classified the histopathological features of KD.⁶ In our case, the histopathological study showed an inflammatory lesion comprising of nodular aggregates of lymphoid tissue admixed with plenty of eosinophils. These nodules were separated by dense interstitial fibrosis. The lymphoid aggregates contained many reactive lymphoid follicles having prominent germinal centers. Plenty of mature eosinophils were present, both intermixed with lymphoid cells and also with zones of fibrosis. Hyalinized vessels were also present. Salivary gland duct and acini were focally present, surrounded by lymphoid cells and eosinophils. The differential diagnoses include angio-lymphoid hyperplasia with eosinophilia (ALHE), Hodgkin's disease, Kaposi sarcoma, eosinophilic granuloma, epithelioid haemangioma, Castleman's disease, tuberculosis, dermatopathic lymphadenopathy, lymphadenopathy of drug reactions, parasitic lymphadenitis, eosinophilic granuloma and epithelioid haemangioma.¹²

There is no standardized treatment protocol present for KD. Treatment modalities include surgical resection, cytotoxic and radiation therapy, as well as regional or systemic steroid therapy.¹⁴ The role of surgery is mainly for diagnostic and cosmetic purposes. Systemic corticosteroids can be used with or without other treatment modalities. Relapses are common and the recurrence rate is as high as 40%, despite early initiation of treatment of patients.¹⁶ Though there is no consensus for the treatment of recurrence, the overall outcome is good as there is no association with malignancy.

Conclusion

Although KD is a rare entity, it should be included in the differential diagnosis for all head & neck swellings. The patient should be assured that although the disease has a high recurrence rate, treatment options are available and the disease is not fatal.

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Bengal Journal of Otolaryngology and Head Neck Surgery
Published by : The Association of Otolaryngologists of India, West Bengal
CMC House, 91B Chittaranjan Avenue, Kolkata - 700073