

Comparison of Ossicular Chain Status by Pre-Operative Cone Beam Computed Tomography (CBCT) with Intra-Operative Findings in Patients with Conductive Hearing Loss

Aarya H Nair¹, Renju Jose², Madhumita Kumar³, Aravind Meena Shanmugham⁴, Beena Varma⁵, Nitin Anand Krishnan⁶, Vijay Kumar S⁷

Original
Article

^{1,2,5}Department of Oral Medicine and Radiology, Amrita School of Dentistry, Amrita Vishwa Vidyapeetham, Kochi, Kerala, ³Department of ENT, Amrita Institute of Medical Science & Research Centre, Amrita Vishwa Vidyapeetham, Kochi, Kerala, ^{4,6}Department of Oral Medicine and Radiology, Amrita School of Dentistry, Amrita Vishwa Vidyapeetham, Kochi, Kerala, India, ⁷Department of Public Health Dentistry, Amrita School of Dentistry, Amrita Vishwa Vidyapeetham, Kochi, Kerala, India.

ABSTRACT

Introduction: Maxillofacial radiology usually confines to the gnathic region and is restricted to the jurisdiction of stomatologists. Recently, the ability of CBCT in maxillofacial imaging other than the dentoalveolar structures has been elucidated, thereby expanding the purview to other areas of medical fraternity especially in the field of Otolaryngology. In contrast to the conventional CT, CBCT is an affordable imaging modality with high area specific resolution and low radiation dose, the properties which could be utilized for imaging of the ear ossicles

Aim: To compare the ossicular chain status from pre-operative CBCT with intra-operative findings in patients with Conductive Hearing Loss (CHL).

Patients and Methods: Between December 2015 and November 2017, a comparative study was conducted among thirty patients diagnosed with Conductive Hearing Loss (CHL). Preoperative Bilateral Ear CBCT scans were acquired using Kodak CS 9300 3D unit. The ossicular chain status from the CBCT scans was interpreted by two radiologists independently and the surgical findings were recorded by an otorhinolaryngologist.

Statistical analysis used: The radio-surgical findings were tabulated and compared using Cohen's Kappa coefficient test.

Results: The agreement between the observers was categorized into poor, moderate, good and excellent. A moderate to good radio-surgical agreement was obtained in the assessment of erosion of all the three ossicles and the ossicular joints. Relation between patient's results and types of graft used showed no statistically significant differences between them.

Conclusion: Considering the advantages, CBCT can be considered as an exceptional substitute for CT in the diagnosis and postoperative follow-up examination of ear pathologies when evaluating bony components, especially in children.

Key Words: Ear ossicles, computerized tomography, conductive hearing loss, Cone beam computed tomography.

Received: 5 February 2022, **Accepted:** 22 March 2022

Corresponding Author: Renju Jose, Department of Oral Medicine and Radiology, Amrita School of Dentistry, Amrita Vishwa Vidyapeetham, Kochi, Kerala, India. **Tel.:** 9995820417, **E-mail:** renjudr@gmail.com

ISSN: 2090-0740, 2022

INTRODUCTION

Hearing loss is a major concern in the day-to-day clinical practice which occurs due to any obstruction in the flow of sound from the external environment to the inner ear. Imaging is a critical step in the evaluation of these patients, specifically to assess the bone erosion and the degree of extension of the disease.^[1] One of the major milestones was marked by the introduction of CBCT in the field of Otorhinolaryngology for temporal bone imaging by Dalchow *et al*^[2]. Prior knowledge of ossicular chain

status decides the likelihood of hearing preservation after surgery^[3].

HRCT is considered as the imaging of choice because of its higher resolution. But the higher cumulative radiation exposure and the expense of the procedure may prevent the patients from acquiring the preliminary investigation. This has posed the need for an imaging modality, which offers high resolution images with least radiation exposure and better economic feasibility to the patients.

CBCT has paved the way for obtaining high spatial resolution along with the ability to restrict the imaged area to the clinically relevant site with the distinct beneficial effects of 3D images^[4]. Numerous studies which compared the CBCT and MDCT show no apparent differences between the two^[5,6]. Only a single study has been reported in the literature, on the evaluation of the utility of CBCT in the assessment of ossicular chain status in patients with Conductive Hearing Loss, highlighting the need for further studies^[1]. Thus the aim of the present study was to assess the efficacy of CBCT in preoperative evaluation of ossicular chain status in patients with Conductive Hearing Loss by comparing with the intraoperative findings.

PATIENTS AND METHODS:

A cross sectional study was conducted among thirty patients diagnosed with Conductive Hearing Loss, in the Department of Oral Medicine and Radiology in collaboration with the ENT department in a tertiary hospital in India. The sample size was estimated considering 5% level of significance and 80% power. The study was conducted between December 2015 and November 2017. Ethical committee clearance (Ref/07/TRPC/2016) was achieved from the institutional board. Written informed consent was obtained from all the patients who were willing to participate in the study and the study was conducted in accordance with the Helsinki declaration.

Patients diagnosed with conductive hearing loss based on the history of presenting illness, clinical examination and pure tone audiometric tests and willing to undergo surgery were included in the study. However, patients with suspicion of malignancy in the ear, congenital ear disease, patients unfit for surgery or anaesthesia, previous history of ear surgeries, history of Head and Neck Radiotherapy, systemic diseases which affect the ear (E.g.: Collagen Vascular/ Granulomatous Diseases) were excluded from the study.

Preoperative bilateral ear CBCT scans with 17*6mm Field Of View (FOV), were acquired using CMOS flat panel detector in Kodak CS 9300 3D unit (Care stream Health Co, Rochester, NY). The imaging parameters were set at 90 kVp, 8 mA, 11.3 seconds, 200 micrometer slice thickness and 0.09 mm voxel size with 1878 mGy/cm² dose area product value. The radiological evaluation was done from the axial and coronal slices of the CBCT. The ossicular chain status from the CBCT was interpreted by two expert maxillofacial radiologists (Observer 1 and Observer 2) independently, who were qualified in the interpretation of temporal bone imaging. The surgical findings were recorded by an experienced oto-rhino-laryngologist. Each ossicle (namely malleus, incus and stapes) was examined for the presence of any erosion in its structure and the ossicular joints (namely malleo-incudal joint and incudo-stapedial joint) were examined for the

presence of any discontinuity in the region of articulation. (Figure 1(a),1(b),1(c))

The various segments of the ossicular chain were assessed as per a scoring system suggested by Pandey *et al*^[7]. Erosion of the ossicles were scored as 0, if erosion was present and score 1, if erosion was absent(ossicles were intact and well defined). The ossicular chain was assessed for the presence of any discontinuity and scored as score 0, if discontinuity was absent and score 1, if discontinuity was present.



Fig. 1(a): CBCT axial scan demonstrating the head of malleus and body of incus in the shape of an “icecream cone”. Note the soft tissue hyperdensity in relation to the internal aspect of the middle ear on the Left side.

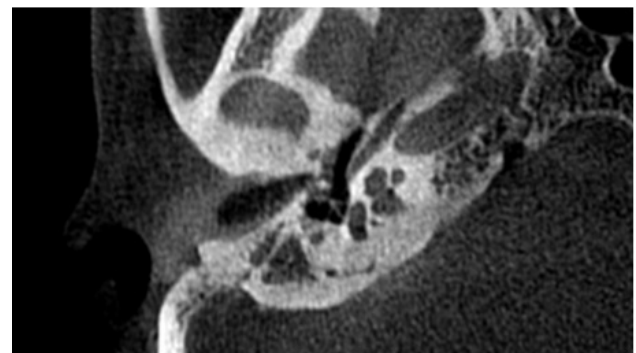


Fig. 1(b): CBCT axial scan showing the stapes superstructure attached to the oval window.

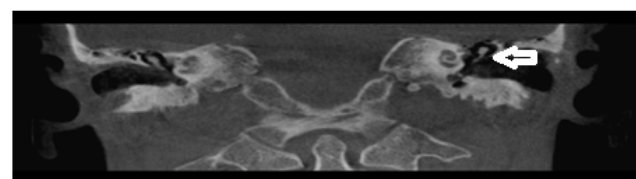


Fig. 1(c): Coronal section of CBCT showing the ossicular chain in continuity.

STATISTICAL ANALYSIS:

The statistical analysis of the data were analyzed using Cohen's Kappa coefficient test, to compare the observations made by the two maxillofacial radiologists from the pre-operative CBCT with the intra-operative observations made by the otorhinolaryngologist. Kappa coefficient scores were categorized as follows: 0–0.4, >0.4–0.6, >0.6–0.8, and >0.8–1.0 indicated poor, moderate, good, and excellent agreement, respectively. p value < 0.05 was considered as statistically significant. Statistical analysis was done using IBM SPSS version 20.0 software Windows (SPSS Inc., Chicago, USA).

RESULTS:

Thirty patients were enrolled in the study with the mean age of 35.2+16 years. The majority of the patients were diagnosed with chronic otitis media (73.3%) and the most common surgical procedure employed was tympanoplasty (63.3%). The frequency distribution of age, gender, site of involvement, symptoms and pure tone audiometry values, diagnosis and procedure undertaken of the patients enrolled in the study is shown in (Table 1).

Table 2 shows the comparison of findings between the two maxillofacial radiologists and the surgical findings reported by the Otorhinolaryngologist. For malleus, both observers from CBCT reported 28 cases which were in agreement with the surgical findings. However, 2 cases were reported differently by the radiologists in comparison with the surgical findings. A good radio-surgical agreement was elicited for the assessment of malleus.

The observations made by the Observer 1 and the ENT surgeon in the assessment of incus were consistently similar in 29 cases, while Observer 2 reported 28 cases which were in agreement with surgical findings. Nevertheless, the observations were dissimilar in one patient by Observer 1 and two patients in Observer 2. However, the radio-surgical agreement between the pre-operative CBCT and intraoperative findings was found to be excellent.

Stapes superstructure was accurately reported in 29 cases by Observer 1. However, the stapes superstructure which was reported to be eroded in one patient from CBCT was found to be intact per-operatively. The agreement between Observer 1 and surgical findings in the assessment of stapes superstructure was found to be good. While Observer 2 reported 25 cases which were consistent with the surgical findings. However, 5 cases were misinterpreted by the Observer 2 from the CBCT

compared to surgical findings, thus owing to a moderate radio-surgical agreement.

The inter-observer agreement in the assessment of ossicular erosion is presented in (Table 3). It is evident that the interpretation of malleus was similar in 28 cases. However, there was disagreement in the interpretation of two cases, where an interpretation of erosion was suggested by one observer in comparison to an intact ossicle by the other. A good agreement was obtained between both maxillofacial radiologists in the evaluation of malleus.

For Incus, similar observations were recorded by the radiologists in 27 cases. Three cases were interpreted differently by the observers. Nevertheless, a good inter-observer agreement was found in the interpretation of incus from CBCT.

The interpretation of stapes showed greater inconsistencies. According to Table 3, similar observations were seen only in 26 cases. Four cases were interpreted differently by both the observers, accounting for a moderate inter-observer agreement.

The ossicular joints were assessed for the presence of any discontinuity. Table 4 demonstrates that one case of malleo-incudal joint and two cases of incudo-stapedial joint were misinterpreted by Observer 2 with that of surgical finding, unlike Observer 1 where all results were interpreted consistently. Thus, the agreement between pre-operative CBCT and intraoperative findings was found to be good to excellent for malleo-incudal joint and moderate for incudostapedial joint. The interobserver agreement for the assessment of ossicular joint discontinuity ranged from moderate to excellent as evident from (Table 5).

Table 1: Frequency distribution of various parameters of the patients enrolled

Variables	N=30 (%)
Age	
11-30 years	14 (46.7%)
31-50 years	9 (30%)
51-70 years	7 (23.3%)
Gender	
Male	17 (56.7%)
Female	13 (43.3%)
Site	
Left	14 (46.7%)
Right	16 (53.3%)
Symptoms	
Reduced hearing	20 (66.7%)
Ear discharge	27 (90%)
Perforation	22 (73.3%)
Ear pain	6 (20%)
Tinnitus	3 (10%)
Pure tone audiometry (Asha <i>et al.</i>)	
Slight (16-25 dB)	4 (13.3%)
Mild (26-40 dB)	11 (36.7%)
Moderate (41-55 dB)	4 (13.3%)
Moderately severe (56-70 dB)	9 (30%)
Profound (>90dB)	2 (6.7%)
Diagnosis	
Canalomastoid fistula	1 (3.3%)
Chronic otitis media	22 (73.3%)
Glomus tumor	1 (3.3%)
Mastoiditis	1 (3.3%)
Otitis media with effusion	2 (6.7%)
Otosclerosis	1 (3.3%)
Traumatic perforation	2 (6.7%)
Procedure undertaken	
Cortical mastoidectomy	1(3.3%)
Modified radical mastoidectomy	2 (6.7%)
Myringotomy with grommet	2 (6.7%)
Stapedectomy	1 (3.3%)
Tympanoplasty	19 (63.3%)
Tympanoplasty with Cortical mastoidectomy	5 (16.7%)

Table 2: Agreement between Observer 1 and 2 and surgical findings in assessment of ossicular erosion from CBCT

			Surgical findings		kappa	<i>p value</i>
			Erosion present	Intact Ossicles		
Observer 1	Malleus	Erosion present	3	1	0.7	<0.001
		Intact Ossicles	1	25		
	Incus	Erosion present	5	1	0.9	<0.001
		Intact Ossicles	0	24		
Stapes	Erosion present	3	1	0.8	<0.001	
	Intact Ossicles	0	26			
Observer 2	Malleus	Erosion present	3	1	0.7	<0.001
		Ossicles intact	1	25		
	Incus	Erosion present	4	1	0.8	<0.001
		Intact Ossicles	1	24		
	Stapes	Erosion present	3	5	0.5	<0.005
		Intact Ossicles	0	22		

Table 3: Agreement between observer1 and observer 2 in assessment of ossicular erosion from CBCT

			Observer 2		kappa	<i>p value</i>
			Erosion present	Intact Ossicles		
Observer 1	Malleus	Erosion present	3	1	0.7	<0.01
		Intact Ossicles	1	25		
	Incus	Erosion present	4	2	0.7	<0.01
		Intact Ossicles	1	23		
	Stapes	Erosion present	4	0	0.6	<0.01
		Intact Ossicles	4	22		

Table 4: Agreement between Observer 1 and Observer 2 with surgical findings in assessment of ossicular joint discontinuity

			Surgical findings		Kappa	<i>p value</i>
			Discontinuity Absent	Discontinuity Present		
Observer 1	Malleo-incudal joint discontinuity	Absent	29	0	1	<0.01
		Present	0	1		
	Incudo-stapedial joint discontinuity	Absent	27	1	0.5	<0.01
		Present	1	1		
Observer 2	Malleo-incudal joint Discontinuity	Absent	29	0	1	<0.01
		Present	0	1		
	Incudo-stapedial joint discontinuity	Absent	27	1	0.5	<0.01
		Present	1	1		

Table 5: Agreement between Observer 1 and Observer 2 in assessment of ossicular joint discontinuity from CBCT

		Observer 2		Kappa	p value	
		Absent	Present			
Observer1	Malleo-incudal joint discontinuity	Absent	29	0	1	<0.01
		Present	0	1		
	Incudo-stapedial joint discontinuity	Absent	28	1	0.7	<0.01
		Present	0	1		

DISCUSSION

Imaging of the maxillofacial region has been progressing with the dawn of various newer modalities. During the last few decades, an exciting new array of imaging techniques has provided the ability to continually upgrade the accuracy of diagnostic task in the maxillofacial region. Recently CBCT is gaining rapid acceptance in maxillofacial radiology as it provides higher information to the clinician with a substantially lower radiation dose to the patient. The cost of examination is low, thereby making the imaging modality feasible for the patients.

The American Academy of Otolaryngology- Head and Neck Surgery had published a position paper, highlighting the characteristics of a point-of-care imaging. According to that, a point-of-care imaging represents a modality of service with high quality care, safe, timely, effective efficient equitable and patient-centered. They strongly recommend that patients should receive the most appropriate imaging modality to help diagnose their condition and that physicians should have the discretion to determine the most appropriate imaging modality for the care of the patient^[8].

Conductive hearing loss is a common clinical scenario in which imaging plays an important role in the pre-surgical evaluation of the disease and providing adequate information regarding the extension of the pathology. Traditionally, the diagnostic imaging of the temporal bone had been accomplished by using standard radiography and of late by HRCT and MRI. Though these imaging systems have their own advantages in serving as an imaging of choice in various conditions, they also have certain inherent disadvantages^[3]. Thus the urge for a less expensive imaging modality with increased spatial resolution and lesser radiation dose to the patient arose, thereby paving the way to the use of CBCT in temporal bone imaging. Numerous studies are reported in the literature, which highlight the role of cone-beam computed tomography (CBCT). One of the distinct advantages of CBCT is the possibility

to restrict the imaged area to the clinically relevant site, thereby making otological imaging possible, since the area from which the information is needed is often limited and unilateral^[4]. Though most of the studies have revealed the advantages of CBCT, limited literature is available on their use in various pathological conditions in the ear.

In our study, the mean age of the patients was 35 years. Similar age distribution was reported in studies by Haidar *et al.* and Albera *et al.*^[9,10].

A male predilection was observed in the study similar to Anglitoiu *et al.*^[11]. This could be because males are more frequently involved in outdoor works and are more prone to atmospheric and climate changes than females. Right side (53.3%) was more affected. Similar side predilection was reported by Varshney *et al.*^[12]. No definite reason could be attributed to it.

Reduced hearing and ear discharge were the common symptoms reported, similar to Haidar *et al.*^[9]. The reason for the higher incidence of discharging ears compared to hearing loss could be because of the difference in appreciating minor changes or degrees of hearing loss by the patient. People usually notice the hearing loss only when the disease has progressed sufficiently enough to cause significant impairment of hearing. The other presenting symptoms included pain, tinnitus and perforation of the tympanic membrane^[12].

The majority of patients were diagnosed with mild conductive hearing loss, followed by 30% cases with moderately severe hearing loss, based on Asha *et al* classification^[13]. Two patients had profound hearing loss, which could be due to the fact that those patients had mixed hearing loss also.

The most common diagnosis among these patients was chronic otitis media (73.3%). Other conditions included were glomus tumor, otosclerosis and otitis media with effusion. The most common surgical procedure employed was tympanoplasty which accounted for 19(63.3%) cases.

In the present study, both CBCT observers reported 28 cases which were in agreement with the surgical findings for the interpretation of malleus. A good agreement was elicited between pre-operative CBCT and surgical findings for the assessment of malleus. O'Donoghue *et al* had described the malleus to be the most resistant ossicle to erosion. The possible reason was attributed to the firm attachment to the tympanic membrane, thereby providing adequate blood flow to the handle^[14]. A good inter-observer agreement was obtained in the current study. Similar radio-surgical agreement was obtained using HRCT by Menon *et al*^[15]. In our study, 2 cases were reported differently by the radiologists in comparison with the per-operative findings. This could be because of the difficulty in the visualization of the ossicular chain owing to the soft tissue surrounding it. A good agreement was obtained between both maxillofacial radiologists in the evaluation of malleus.

Among 30 patients, 5 cases showed erosion of incus peroperatively. According to Haidar *et al*, incus was the commonest ossicle to undergo necrosis. The reasons attributed were the presence of tenuous blood supply and notable bone marrow. In addition, these ossicles are exposed to the external environment once the tympanic membrane is perforated thus making them more vulnerable to undergo erosion. Also, the degree of ossicular chain destruction is dependent on the type of the disease and the duration of the inflammatory process^[9].

Literature review has shown that a higher degree of ossicular involvement was found in active squamous type of chronic otitis media with evidence of cholesteatoma. In our study, the majority of the patients were diagnosed with mucosal type of chronic otitis media. In CSOM, the ossicular erosion occurs by active phenomena of osteoclastic osseous resorption induced by the formation of excessive inflammatory mediators in the tympanic cavity rather than by a passive avascular necrosis^[9].

The findings on incus were reported accurately in 29 cases and 28 cases by Observer 1 and 2, respectively. The radio-surgical agreement between CBCT and peroperative findings was found to be good to excellent. The findings were similar to the results reported by Dalchow *et al*, in which excellent prediction of the ossicular chain status was possible and these findings were helpful in pre-operative diagnosis and management of these patients^[2]. But unlike the study conducted by Dalchow *et al* the present study had assigned two observers for the evaluation of the CBCT scans preoperatively so as to determine the level of agreement between different observers in analyzing the CBCT findings. In the present study, the

inter-observer agreement in the evaluation of incus was found to be good, since only 3 cases were reported inconsistently by the radiologists.

The stapes superstructure was found to be intact in 27 cases while it was found to be eroded in 3 cases peroperatively. However, the erosion of stapes was reported consistently 29 cases by Observer 1 and in 25 cases by Observer 2. In the present study the stapes superstructure which was reported to be completely eroded in CBCT was found to be intact per-operatively. Nevertheless, inconsistencies in the interpretation of stapes were observed between the observers from CBCT, owing to a moderate inter-observer agreement. Similar observations were reported in the HRCT study by Datta *et al*. According to them, the stapes usually appeared as a soft tissue hyperdensity in the region of oval window niche. Thus, it was difficult to distinguish between the destruction of the stapes and the soft tissue surrounding it^[16].

In the cadaver study conducted by Peltonan *et al*, all the structures including stapes were observed equally well in CBCT and MSCT and no apparent difference was found in the interpretation of the findings between the observers. In the present study, a moderate inter-observer agreement was observed in the assessment of erosion of malleus and stapes. The authors have highlighted that because of the greater tissue between the source and the detector, the imaging of an actual patient is associated with the occurrence of image artefacts. These artefacts could be in the form of beam hardening, scattering etc. Also, a low contrast resolution has been found in CBCT as all the attenuating structures of the patient are generally included in the scan FOV^[4].

29 cases had an intact malleo-incudal joint and incudo-stapedial joint peroperatively. The findings on malleoincudal joint were reported consistently with surgical findings in all cases by both the observers. Although, 28 cases were reported accurately by both the observers from CBCT, two cases were misinterpreted by both the observers from CBCT. The interobserver agreement was found to be excellent for the assessment of malleo-incudal joint and good for incudostapedial joint discontinuity. These agreement in the ossicular joint discontinuity assessment was in accordance with Dahmani *et al* study, who had shown that the CBCT provides high resolution and density contrast for fine bone structures^[5].

One of the most important features of special interest in CBCT is the availability of inherent slice thickness as less as 180 micro-meters; in contrast to 1mm slice thickness in CT. Isono *et al* had stated that, a section inter-space of 1.0 mm facilitated appropriate

assessment of minute ossicular segments and their continuity^[17]. Though HRCT has the advantage of providing sub-millimetre slice thickness, a higher radiation may be required for acquiring the images with finer details.

Another striking observation that could be appreciated in the study was that the extent of the soft tissue in the middle and external ear cavity could be appreciated well in the CBCT scans, although the exact characterization of the soft tissue, as to whether it is cholesteatoma or granulation tissue or cerumen could not be carried out. Similar observation was made in HRCT by Sudarshan *et al*, who pointed out that HRCT is less sensitive in differentiating cholesteatoma from granulation tissue^[18]. This is of clinical importance as CBCT offers less radiation dose to the patient and could be utilized in imaging with comparable diagnostic quality as HRCT. Rather, Thews *et al* had suggested that the CBCT had almost the same diagnostic value as CT but the soft tissue contrast was not sufficient enough for clinical utility^[19].

CONCLUSION

Considering the advantages of lower radiation level, patient compliance and cost of examination, CBCT can be considered as an exceptional substitute for the diagnosis, postoperative follow-up examination in ear cases, especially for imaging in children. However, precise knowledge of the normal anatomical landmarks and associated pathologies with good clinical experience is required in the accurate interpretation of temporal bone imaging.

CONFLICT OF INTEREST

There are no conflicts of interest.

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