Comparison of Magnetic Resonance Imaging and CT scan based delineation of target volumes and organs at risk in radiation treatment planning of head and neck malignancies

## Introduction

Malignancies of head and neck are a significant health problem in India comprising approximately one-third of all cancer cases. The increase in incidence in use of tobacco over the last few decades has led to an increase in incidence of tobacco- related malignancy in India.(1)

With 77,000 cases diagnosed per year, head and neck malignancies are the second most common cancers in the Indian population.(2)The important risk factors associated with malignancies of head and neck comprise of smoking, alcohol, betel quid, infection by human papilloma virus and Epstein-Barr virus. Cigarette smoking and alcohol consumption have a synergistic effect in leading to the development of head and neck cancer. The standard modality of treatment of head and neck malignancies includes radiation therapy also.

The two main modalities of radiation treatment and external beam radiation therapy (EBRT) where the radiation is delivered to the patient from an external source, and brachytherapy where the radiation is delivered internally inside the body using radioactive implants.

The various modalities of EBRT includes:

- 3DCRT- It is planned using 3D images, such as CT or MRI, and the radiation beams are shaped (conformed) to the tumour.
- IMRT- It is intensity modulated radiotherapy where the intensity of the beams used to treat the tumour can be varied in order to shape the dose very precisely to the tumour.
- Stereotactic radiation therapy- It conforms extremely precisely to the tumour and gives very high accuracy. Stereotactic radiation therapy can be used to treat brain, early stage lung, pancreatic, and prostate tumours. When it is used to treat tumours that are not in the brain, it can also be referred to as stereotactic body radiation therapy (SBRT) or stereotactic ablative radiation therapy (SABR).

Hence, conformal radiotherapy describes radiotherapy treatment that creates high-dose volumes that are shaped to closely "conform" to the desired target volumes and prescription doses while minimizing (as much as possible) the dose to the critical normal tissues. Hence the term "conformal" is applied to treatment plans in which (1) target volumes are defined in three dimensions using contours drawn on many slices from an imaging study (2) multiple beam targets are used to cross fire on the targets (3)the individual beams are shaped or intensity modulated to create a dose distribution that conforms (in shape and dose) to the target volume shapes and desired dose levels (in case of IMRT) (4) appropriate use of image guidance, accurate patient setup and immobilization, management of motions and other changes to ensure accurate delivery of the planned dose distributions to the patient, so that deviations from the planned treatment of the patient can be minimized(in case of IGRT)(3)

A number of different treatment planning techniques and various treatment delivery techniques are routinely used to perform clinical conformal therapy.(4) The three dimensional conformal therapy(3DCRT) was the first conformal therapy technique developed, based on the use of three-dimensional treatment planning and multiple cross-firing, carefully shaped fixed fields. A more recent planning method-inverse planning-involves creation of the radiotherapy plan using mathematical optimization techniques. The combination of inverse planning and intensity-modulated beams is called intensity modulated radiation therapy-IMRT. However, it was not until the 1950s and 1960s that techniques recognizable as modern conformal therapy began to be developed.

One of the main limitations for the conformal delivery techniques was treatment planning. The introduction of CT in the early 1970s was key to the development of modern 3D planning that is crucial to conformal therapy because it made available a complete 3D description of the anatomy of each patient that could be the basis for planning.(4)Other imaging data including magnetic resonance imaging (MRI) and positron emission tomography (PET), also became available and began to be used for planning in the mid 1980s(3)

With the use of techniques like IMRT, it has now become possible to deliver highly precise, conformal doses of radiation to the tumour; accurate delineation of target volume is hence highly crucial in this technique.(5)Accuracy of target definition is paramount in radiation treatment planning, especially in the head and neck region because of its anatomical complexity. Traditionally the GTV (Gross Tumour volume) is defined as evident disease and nowadays, efforts to improve GTV delineation have been helped considerably with the evolution of new imaging modalities. (4)The optimal choice of the imaging modality to accurately define the GTV in patients with locally advanced head and neck squamous cell carcinoma is still debatable. So we plan to study the comparison of MRI and CT scan based delineation of target volume and OARs (Organs At Risk) in head and neck cancers treatment planning.

### Review of literature

In the present era, IMRT is the standard of radiation delivery for head and neck malignancy and hence the accuracy of tumour delineation is pertinent.(6) The conventionally used imaging modality to delineate the tumour is CT. The use of MRI in delineating the accurate extent of the malignancy would lead to precise delivery of radiation dose to GTV and lesser dose to the surrounding normal tissues. (7)While planning CT provides the geometric integrity and relative electron density crucial for dose calculation, MRI co-registration to the planning CT is becoming indispensable due to precise contouring in head and neck malignancies owing to the improved soft tissue contrast.(8)

In a study of advanced head and neck malignancies conducted by Chauhan et al, CT, MRI and FDG-PET was used to delineate the tumour. There was a mean decrease in GTV volume by 4.79 cc on MRI and mean increase in GTV volume by 2.4 cc on PET. There was no statistically significant difference between GTV obtained by PET and CT. The difference in GTV volume between CT and MRI may be due to inclusion of areas which were highly doubtful on CT scan but better delineated in MRI. The study reveals that if GTV is delineated on three different modalities, volumes differed significantly, when compared on CT and MRI and MRI and PET-however volumes did not differ significantly by CT and PET. Smaller target volumes lead to smaller treatment volume and hence the use of MRI improves accuracy of tumour delineation, reduces the chances of uncertainities and hence effectively reduces the risk of local recurrence.(9) Hence, the use of a single imaging modality for target volume delineation is inadequate with limitations pertaining to the particular imaging modality being used and hence the combined use of imaging modalities compensates for the shortcomings of the other, resulting in better target volume delineation.(10)

In another study by T. Schakel et al, tumour volume was delineated using DW-MRI and FDG- PET. The delineated volumes on DW- MRI were found to be significantly larger than FDG –PET with median volume of 10.8 cc and 8 cc respectively. The largest difference between the two imaging modalities were found in tumours adjacent to the lymphatics. Both DW-MRI and PET are prone to show false positive results in these tissues, as both DW-MRI and FDG-PET show restricted tumour behaviour and increased FDG uptake.(11)

The study by Bird et.al used CT,MRI and FDG- PET for target volume delineation. The primary tumour volume obtained was larger on MRI than CT. GTV obtained in PET was significantly smaller than those obtained in MRI. The study concludes that using CT,MRI and PET produced significantly different GTV. These data suggests that the implementation of combined imaging modalities for planning of

radiotherapy would have considerable impact on dose to the tumour and organs at risk.(12)

The study done by Natalia et al used FDG- PET and MRI for GTV delineation. The study concludes that GTV- MRI was larger than the reference GTV-CT in 80 % of patients, which might be due to better soft tissue imaging and accurate definition of the tumour's boundary, due to higher soft tissue contrast and infiltration increased resolution of anatomic structures. 40% of the GTV-PET were larger than the reference GTV-CT, this may be due to increased DG uptake by surrounding tumour areas of necrosis and inflammation. This study took into consideration only lymph nodes which were suspicious for malignancy based on all three imaging methods to prevent false positive results obtained by FDG-PET as it would lead to overstaging the patients with inflammatory and necrosed lymph nodes as malignant. In case of metastatic lymph nodes, CT and MRI have comparable sensitivity and specificity of 50-80% and 70-90% respectively.(13)

The study done by Houda et.al says use of MRI in RT planning has lead to reduction of interobserver variability of both GTV and OAR. MRI had higher detection of intracranial and pterygopalatine fossa infiltration and also perineural spread which leads to improved tumour delineation and staging compared to CT. This study hence aims to compare the gross tumour volume obtained on CT and MRI to highlight the importance of incorporating multiple imaging modalities for tumour delineation keeping in mind the importance of clinical examination as well.(14)

## Aims & Objectives

### Aim

To compare MRI and CT scan based delineation of gross target volume and organs at risk in Radiation planning of head and neck cancers.

### Objective

- 1. To compare the gross tumour volume obtained by contouring in CT and MRI imaging
- 2. To compare the delineation of organs at risk (brainstem, spinal cord, parotid glands, submandibular glands and pharyngeal constrictor muscles) in CT and MRI scan.

### Primary outcome

Concordance in CT and MRI contouring of target volumes and OARs

## Material and Methods

<u>Place of study</u>- Department of Radiation Oncology, AIIMS Rishikesh <u>Duration of study-</u> January 2020 to September 2021 <u>Study design</u>- Cross sectional study <u>Sample size</u>- 54

The sample size was calculated using G-Power software taking a mean difference of 0.8 and standard deviation difference of 2, taking reference from previous literature. Alpha is taken as 0.05 and power of 0.80.

Inclusion criteria

The inclusion criteria for the study is:

- 1. Newly diagnosed biopsy proven head and neck cancers.
- 2. Age more than 18 years

- 3. Eastern Co-operative Oncology Group (ECOG) performance status of 0-2
- 4. Normal kidney function test

## Exclusion criteria

- 1. Poor performance status of ECOG 3-4
- 2. Deranged serum creatinine and blood urea
- 3. Presence of metal elements in patient's body which are MRI incompatible
- 4. Allergy to CT or MRI contrast
- 5. Second primary/ recurrent head and neck cancer
- 6. Patients who have undergone tracheostomy

## Study methodology

The study will be conducted on the patients presenting to the department of Radiation Oncology, AIIMS Rishikesh. Eligible patients will be explained in detail about the purpose of the study and will be enrolled in the study after an informed consent is obtained.

#### Pre- treatment staging and workup

- 1. Detailed clinical history and physical examination
- 2. Assessment of performance status
- 3. Biopsy from the lesion
- 4. Fine needle aspiration cytology of neck nodes, if present
- 5. Complete haemogram, liver function test, kidney function test
- 6. Chest X-ray
- 7. Fine needle spiration of suspicious neck nodes with or without USG neck
- 8. Staging as per AJCC Cancer Staging Manual Eighth Edition,
- 9. Dental evaluation
- 10. Assessment of nutritional status

#### Immobilization and CT simulation

Patients will be immobilized in supine position with hands on the side with a 5 clamp thermoplastic head and neck cast and neck rest. CT scan for RT planning will be done on GE Optima machine with bore size of 70 cm with 2.5 mm slice thickness. Intravenous lohexol contrast will be given intravenously and contrast enhanced CT scan will be done from vertex of skull to carina. The CT image will be then imported from simulation system to treatment planning system (MONACO).

#### MRI

RT planning MRI scan will be done on GE Discovery 3T system with bore size of 70 cm. Axial post- contrast T1- weighted and axial fat saturated T2- weighted sequences will be acquired in treatment position with 1 mm slice thickness using a customised head and neck thermoplastic cast and the same neck rest used for CT scan, for neckchin distance. positional replication and maintenance of Intravenous Gadolinium will be given as contrast and scan will be taken from vertex of skull to carina. This MRI image obtained in DICOM format on a CD will be loaded into our CT simulation system and then imported to MONACO system.

### Fusion and registration

Rigid image registration of planning CT scan image will be done with MRI image and fusion accuracy will be ensured by manual adjustment as well between the CT dataset and the T1 –weighted MR dataset.

### CT/MRI target volume contouring

The following volumes will then be delineated based upon ICRU 83 on the CT and MRI images based on site and stage of the disease by one observer only.

 Gross Tumour Volume primary and nodal (GTVp and GTVn): Gross primary tumour and enlarged regional lymph nodes determined from clinical information, radiological and endoscopic findings.

CT/MRI Organs at Risk (OAR) contouring:

 Organs at Risk (OAR): Organs at risk will include spinal cord, brain stem, parotid gland, submandibular gland, pharyngeal constrictor muscles The various OARs and target volumes will be contoured in CT and MRI images using OAR contouring guidelines.

## Volume Analysis

GTV defined on CT image (GTV-CT) will be compared with GTV acquired on MRI image( GTV-MRI) and volumetric evaluation will be performed. GTVp (primary) and GTVn (nodal) volumes will be compared for both CT and MRI.

The volumes and intersection of both primary and nodal GTV-CT and GTV-MRI contours will be recorded to calculate the Dice similarity coefficient (DSC), a validated metric to evaluate spatial overlap between two volumes. The DSC is calculated using the equation:  $2 \times (A \cap B)/(A + B)$ , where A and B represent two volumes,  $(A \cap B)$  represents the volume of intersection, and (A + B) represents the absolute sum of their volumes. A DSC  $\geq$ 0.7 has been reported as a "good" overlap.

Conformity Index (CI) will be calculated. It refers to the ratio of the volume of overlap between outlines to the volume encompassing the full extent of both outlines. It can be calculated as  $(A \cap B)/(A \cup B)$ . Two perfectly

concordant volumes will have a CI of 1, and two volumes that fail to overlap have a CI of 0.

Sensitivity index (Se Idx); and inclusion index (Incl Idx)will be calculated: Se Idx and Incl Idx calculate the overlap volume between the test (CT) and reference (MRI) contours as a percentage of either the test or reference contours for Incl Idx and Se Idx, respectively. Both indices vary between 0 and 1, with a value of 1 indicating a perfect overlap. The Se Idx will be measure of the probability that the MRI contour matches the CT manual contour. *The* Incl Idx is the probability that a voxel of the MRI is really a voxel of the CT manual contour.

Sensitivity index: (A  $\cap$  B/ A ) x 100

Inclusion index: (A  $\cap$  B/ B ) x 100

Metrics quantifying variation in OARs will be coefficient of variation of OARs volume (i.e., standard deviation/mean) and Dice coefficient

### Statistical analysis

The demographic details will be described and the outcome parameters will be described as mean with standard deviation or median with range as applicable. Statistical analysis will be done using Paired t-test or Wilcoxon signed rank test as applicable.

## Conflict of interest

There has been no conflict of interest.

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## Annexure I

### Informed Consent Form

Patient ID No for this study:

**Study Title**: Comparison of Magnetic Resonance Imaging and CT scan based contouring of target volumes and Organs at risk in Head and Neck Malignancies

The information regarding the study has been explained to me in detail in a language that I comprehend and I have fully understood the contents. I understand that information collected about me from my participation in this study and sections of any of my medical notes may be looked at by responsible individuals from AIIMS.

I agree to take part in the above study.

(Signature/Left Thumb Impression)

Witness signature Name Address

Name	of	Participant:
Son / Daughter / Spous	e of:	
Address:	Phone No:	
A	NNEXURE II (अनुलग्न	रक II)
सूचितसहमतिप्रपत्र		
इसअध्ययनकेलिएरोगीआईउ	डीसंख्या :	
अध्ययनकाशीर्षक :		
चुंबकीयअनुनादइमेजिंगऔर	सीटीस्कैनकीतुलनाटारगेटवॉल्यूमवे	pसमोच्च औरसिर और गर्दन
कीविकृतियोंमेंजोखिमवालेअ	गोंकी	
अध्ययनकेबारेमेंजानकारीमु	<u>झे</u> एकऐसीभाषामेंविस्तारसेबताईगई	हैजिसेमैंसमझरहाहूंऔरमैंपू
रीतरहसेसामग्रीकोसमझगय	हिं।	
मैंसमझताहूंकिइसअध्ययनमे	मेरीभागीदारीसेमेरेबारेमेंएकत्रकीग	ईजानकारीऔरमेरेकिसीभी
मेडिकलनोटकेवर्गींकोएम्सवे	ञ्जिम्मेदारव्यक्तियोंद्वारादेखाजासक	न्ताहै।
मैंउपरोक्तअध्ययनमेंभागलेने	किलिएसहमतहूं।	
(हस्ताक्षर / वामअंगूठाछ	 ।प) साक्षीहस्ताक्षर	

नाम

पता

## प्रतिभागीकानाम:

पुत्र / पुत्री / पति / पती:	
पता:	
फोननंबर:	

# Annexure III

## Patient Proforma

CASE No	RT OPD No	
Date of first visit:	Date of last follow up:	
BIODATA:		
Name:	Age:	Sex:
Occupation:	Income:	
Address:		
Marital status:		
Rural/Urban:	Socio economi	c status:
CHIEF COMPLAINTS		
PERSONAL HISTORY		
Alcoholism:	Smoking:	
Dietary habits:	Any other:	
PAST HISTORY		
FAMILY HISTORY		
PREVIOUS TREATMENT HISTORY	ſ	
HISTORY OF ASSOCIATED DISEA	SE	
EXAMINATION:		
General Physical Examination		
ECOG Performance Status		
Local Examination:		



Indirect laryngoscopy:

Direct Laryngoscopy (where necessary):

Local/ regional lymph

nodes

Any other relevant positive systemic examination:

Histopathology report:

Clinical Diagnosis:

Clinical stage as per AJCC Staging Manual 8th Edition 2018 INVESTIGATIONS

Complete haemogram

Kidney function test

Liver function test Radiological investigations CT scan X ray chest USG abdomen Any other investigations

## Annexure IV

## Eastern Cooperative Oncology Group (ECOG)

## Performance Scale

GRADE	Description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair
5	Dead

## Annexure V American Joint Committee on Cancer (AJCC-8th) TNM Staging System

### PRIMARY TUMOUR (T)

Тх	Primary tumour cannot be assessed
ТО	No evidence of primary tumour
Tis	Carcinoma in situ

#### ORAL CAVITY

T1	Tumour ≤2 cm, ≤5 mm depth of invasion (DOI)
	DOI is depth of invasion and not tumour thickness.
T2	Tumour ≤2 cm, DOI >5mm and ≤10mm
	<i>Or</i> Tumour >2 cm but ≤4 cm and ≤10mm DOI
Т3	Tumour >4 cm or any tumour >10mm DOI
T4a	Moderately advanced local disease. Tumour invades
	<ul> <li>Cortical bone of maxilla or mandible</li> </ul>
	Maxillary sinus or
	Skin of face
T4b	Very advanced local disease Tumour invades
	Masticator space
	Pterygoid plates
	Skull base and/or
	<ul> <li>Encases internal carotid artery</li> </ul>

## OROPHARYNX HPV mediated p16+ve

T1	Tumour 2 cm or less in greatest dimension
T2	Tumour> 2 cm but < 4 cm in greatest dimension
Т3	Tumour> 4 cm in greatest dimension or extension to lingual
	surface of epiglottis
T4	Moderately advanced local disease. Tumour invades the
	<ul> <li>larynx,</li> </ul>
	extrinsic
	muscle of Tongue
	<ul> <li>medial pterygoid,</li> </ul>
	<ul> <li>hard palate or</li> </ul>
	mandible

### OROPHARYNX HPV mediated p16-ve

T1	Tumour 2 cm or less in greatest dimension
T2	Tumour> 2 cm but < 4 cm in greatest dimension
Т3	Tumour> 4 cm in greatest dimension or extension to lingual
	surface of epiglottis
T4a	Moderately advanced local disease. Tumour invades
	• larynx,
	extrinsic
	muscle of Tongue
	<ul> <li>medial pterygoid,</li> </ul>
	hard palate or
	mandible
T4b	Very advanced local disease Tumour invades
	<ul> <li>lateral pterygoid muscle,</li> </ul>
	Pterygoid plates
	<ul> <li>lateral nasopharynx</li> </ul>
	<ul> <li>or skull base or</li> </ul>
	<ul> <li>encases carotid artery</li> </ul>

#### HYPOPHARYNX

T1	Tumour limited to one subsite of hypopharynx and/or 2 cm or
	less in greatest dimension
T2	Tumour invades more than one subsite of hypopharynx, >
	2cm but < 4 cm in greatest dimension without fixation of
	hemilarynx
T3	Tumour> 4cm in greatest dimension or with fixation of
	hemilarynx or extension to esophagus
T4a	Moderately advanced local disease (Tumour invades
	thyroid/cricoid cartilage hyoid bone, thyroid gland, or central
	compartment soft tissue)
T4b	Very advanced local disease (Tumour invades prevertebral
	fascia, encases carotid artery, or involves mediastinal
	structures

#### SUPRAGLOTTIS

T1	Tumour limited to one subsite of supraglottis with normal cord mobility
T2	Tumour invades mucosa of > 1 adjacent subsite of supraglottis or glottis or region outside the supraglottis without fixation of larynx
Т3	Tumour limited to larynx with vocal cord fixation and/or invades any of post cricoid area, pre-epiglottic space, paraglottic space, and/or inner cortex of thyroid cartilage
T4a	Moderately advanced local disease (Tumour invades through the thyroid cartilage and/or tissues beyond the larynx)
T4b	Very advanced local disease (Tumour invades prevertebral space, encases carotid artery, or invades mediastinal structures)

GLOTTIS

T1a	Tumour limited to one vocal cord with normal mobility
T1b	Tumour involves both vocal cords with normal mobility
T2	Tumour extends to supraglottis and/or subglottis, and/or with
	impaired vocal cord mobility
T3	Tumour limited to the larynx with vocal cord fixation and/or
	invasion of
	Paraglottic space, and/or inner cortex of thyroid cartilage
T4a	Moderately advanced local disease (Tumour invades through
	outer cortex of thyroid cartilage and/or tissues beyond the
	larynx)
T4b	Very advanced local disease (Tumour invades prevertebral
	space, encases carotid artery, or invades mediastinal
	structures)

#### SUBGLOTTIS

T1	Tumour limited to the subglottis
T2	Tumour extends to vocal cord(s) with normal or impaired
	mobility
T3	Tumour limited to larynx with vocal cord fixation
T4a	Moderately advanced local disease (Tumour invades
	cricoid/thyroid cartilage and/or tissues beyond the larynx)
T4b	Very advanced local disease (Tumour invades prevertebral
	space, encases carotid artery, or mediastinal structures)

## REGIONAL LYMPH NODE (N)

Nx	Regional lymph node cannot be assessed
N0	No regional lymph node metastasis
N1	Metastasis in a single ipsilateral lymph node, 3 cm or less
	in greatest dimension
N2a	Metastasis in a single ipsilateral lymph node, more than 3
	cm but less than 6 cm in greatest dimension

N2b	Metastasis in a multiple ipsilateral lymph nodes, < 6 cm in
	greatest dimension
N2c	Metastasis in bilateral or contralateral lymph nodes, < 6 cm
	in greatest dimension
N3	Metastasis in a lymph node more than 6 cm in greatest
	dimension

### DISTANT METASTASIS (M)

MO	No distant metastasis
M1	Distant metastasis

### ANATOMIC STAGE/PROGNOSTIC GROUPS

Stage 0	Tis	NO	MO
••••;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;;			
Stage I	T1	N0	MO
Stage II	T2	N0	MO
Stage III	Т3	N0	MO
	T1,2,3	N1	MO
	T4a	N0,1	MO
Stage IVA	T1,2,3,4a	N2	MO
Stage IVB	any T	N3	MO
	T4b	any N	MO
Stage IVC	any T	any N	M1

## ANNEXURE VI

## OAR contouring guidelines

**Brainstem:** Brainstem The cranial border of the brainstem is defined as the bottom section of the lateral ventricles, the caudal border as the tip of the dens of C2 (cranial border of the spinal cord). The bottom section of the lateral ventricles is clearly visible on both CT and MRI.

**Spinal cord:** spinal cord is delineated as the true spinal cord, not the spinal canal. The cranial border was defined at the tip of the dens of C2 (the lower border of the brainstem), and the caudal border at the upper edge of T3. With caudally located tumours or lymph node areas, extending the spinal cord contours by at least 5 cm caudal to the PTV.

Organ at risk	Remarks	Anatomic boundaries					
		Cranial	Caudal	Anterior	Posterior	Lateral	Medial
Parotid gland	Include carotid artery, retromandibular vein and extracranial facial nerve.	External auditory canal, mastoid process	Post, part submandibular space	Masseter m., post. border mandibular bone, med. and lat. pterygoid m.	Ant. belly stemocleidomastoid m., lat. side post. belly of the digastric m. (posterior- medial)	Subcutaneous fat, platysma	Post, belly of the digastric m, styloid process, parapharyngeal space
Submandibular gland		Med. pterygoid m., mylohyoid m.	Fatty tissue	Lat. Surface mylohyoid m., hyoglossus m.	Parapharyngeal space, stemocleidomastoid m.	Med. surface med. pterygoid m., med. surface mandibular bone, platysma	Lat. surface mylohyoid m., hyoglossus m., superior and middle pharyngeal constrictor m., anterior belly of the digastric m.
Pharyngeal constrictor muscle	Thickness ~3 mm	Caudal tips of pterygoid plates	Caudal edge of arytenoid cartilages	Superior: hamulus of pterygoid plate; mandibula; base of tongue; pharyngeal lumen. Middle: base of tongue; hyoid. Inferior: soft tissue of supraglottic/glottic larynx	Prevertebral muscle	Superior: medial pterygoid muscle. Middle: greater hom of hyoid bone. Inferior: superior hom of thyroid cartilage	λ.

Organs at risk with specification of anatomic boundaries. Ant. = anterior, post. = posterior, lat. = lateral, med. = medial, m. = muscle.

## ANNEXURE VII

## **Patient Information Document**

You are being invited to take part in this study. Before enrolling yourself in this study, it's important that you read and understand the following information.

#### **STUDY TITLE**

Comparison of Magnetic Resonance Imaging and CT scan based delineation of target volumes and Organs at risk in Head and Neck Malignancies

#### INTRODUCTION

Malignancies of head and neck are a significant health problem in India comprising approximately one-third of all cancer cases. Radiation treatment is the standard modality of treatment in head and neck malignancies. In the present scenario, the tumour is treated using a technique called IMRT and the imaging modality used for treatment planning purpose is CT. For better soft tissue delineation MRI is better. So we plan to study the comparison of MRI and CT scan based delineation of target volume and OARs (Organs At Risk) in head and neck cancers. The use of MRI in delineating the accurate extent of the malignancy would lead to precise delivery of radiation dose to GTV and lesser dose to the surrounding normal tissues.

#### PURPOSE OF STUDY

To compare the GTV and delineation of organs at risk obtained by contouring in CT and MRI imaging

#### METHOD

Patients will be immobilized in supine position with hands on the side with a 5 clamp thermoplastic head and neck cast and neck rest. CT scan for RT planning will be done. RT planning MRI using a customised head and neck thermoplastic cast and the same neck rest used for CT scan, for positional replication and maintenance of neck- chin distance.

#### CONFIDENTIALITY

All information collected about you during the course of study will be kept strictly confidential. Any publication of this data will not identify you by name. By signing the Informed Consent form, you authorize the study investigator to release your study related medical records to the regulatory authorities and Institutional Ethics Committee if required.

#### CONTACT FOR FURTHER INFORMATION

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## ANNEXURE VIII (अनुलग्नक VIII)

## रोगीसूचनादस्तावेज

आपकोइसअध्ययनमेंभागलेनेकेलिएआमंत्रितकियाजारहाहै।इसअध्ययनमेंखुदकोनामांकित करनेसेपहले, यहमहत्वपूर्णहैकिआपनिम्नलिखितजानकारीपढ़ेंऔरसमझें।

अध्ययनकीस्थिति

चुंबकीयअनुनादइमेजिंगऔरसीटीस्कैनआधारितहेडऔरगर्दनकीविकृतियोंमेंजोखिमवालेल क्ष्यसंस्करणोंऔरअंगोंकीस्कैनकीतुलना

### परिचय

भारतमेंसिरऔरगर्दनकीखराबीएकमहत्वपूर्णस्वास्थ्यसमस्याहै,

जिसमेंसभीकैंसरकेलगभगएक-तिहाईमामलेशामिलहैं।

विकिरणउपचारसिरऔरगर्दनकीदुर्दमताओंमेंउपचारकीमानकमात्राहै।वर्तमानपरिदृश्यमें, ट्यूमरकाइलाजआईएमआरटीनामकएकतकनीककाउपयोगकरकेकियाजाताहैऔरउपचार नियोजनउद्देश्यकेलिएउपयोगकिएजानेवालेइमेजिंगमोडिटीसीटीहै।बेहतरनरमऊतककेलिए डेलिनेशनएमआरआईबेहतरहै।इसलिएहमसिरऔरगर्दनकेकैंसरमेंएमआरआईऔरसीटीस्कै नआधारितटारगेटवॉल्यूमऔरओएआर (ऑर्गेन्सएटरिस्क) कीतुलनाकेअध्ययनकीयोजनाबनातेहैं।एमआरआईकाउपयोगअसाध्यसीमातकसटीकरूपसे करनेमेंहोताहैजिससे

कोविकिरणखुराककीसटीकडिलीवरीहोतीहैऔरआसपासकेसामान्यऊतकोंकोकमखुराकमि लतीहै।

## अध्ययनकेअवसर

सीटीऔरएमआरआईइमेजिंगमेंसमोच्चद्वाराप्राप्तजोखिमपरजीटीवीऔरअंगोंकेपरिसी मनकीतुलनाकरना

## तरीका

मरीजोंको

क्लैंपथर्मोप्लास्टिकसिरऔरगर्दनकेकास्टऔरगर्दनकेबाकीहिस्सोंकेसाथहाथोंसेलापर वाहस्थितिमेंडुबोयाजाएगा।आरटीयोजनाकेलिएसीटीस्कैनकियाजाएगा।आरटीकीयो जनाबनाएमआरआईएकस्वनिर्धारितसिरऔरगर्दनथर्माप्लास्टिककास्टऔरएकहीगर्द नबाकीसीटीस्कैनकेलिएइस्तेमालकिया,

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स्थितिप्रतिकृतिऔरगर्दनकेठोड़ीदूरीकेरखरखावकेलिए।

गोपनीयता

अध्ययनकेदौरानआपकेबारेमेंएकत्रकीगईसभीजानकारीकोकड़ाईसेगोपनीयरखाजाए गा।इसडेटाकाकोईभीप्रकाशनआपकोनामसेनहींपहचानेगा।सूचितसहमतिफॉर्मपरह स्ताक्षरकरके ,

आपअध्ययनअन्वेषककोआवश्यकतापड़नेपरनियामकअधिकारियोंऔरसंस्थागतआ चारसमितिकोअपनेअध्ययनसंबंधीचिकित्सारिकॉर्डजारीकरनेकेलिएअधिकृतकरतेहैं।

अन्यजानकारीकेलिएसंपर्ककरें

डॉ।लीक्ष्मीआर विकिरणऑन्कोलॉजीओपीडी एम्सऋषिकेश नहीं: 7550319166