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Annexure-I

ETHICS COMMITTEE CERTIFICATE

Swami Rama Himalayan University

Swami Ram Nagar,
P.O. Jolly Grant, Dehra dun 248016 (INDIA)
Phone: 91-135-2471111, Extn. 328, Fax 910135-24711122

"Ethics Committee"
CDSCO Reg. No. ECR/1741/Inst/UK/2022
ICMR Reg. No. EC/NEW/INST/2022/UA/0152

SRHU/HIMS/E-1/2023/54

Date: 30/03/2023

To,

Ravi Kant,
Ph.D Scholar,
under the guidance of Dr. Meenu Gupta.
Professor, Deptt. of Radiation Oncology,CRI, HIMS,
Swami Rama Himalayan University

Ref: (Ph. D Synopsis): Dosimetric evaluation in carcinoma lung by intraluminal brachytheripy and correlation in phantom model. Dosimetric evaluation in carcinoma lung by intraluminal brachytheripy and correlation in phantom model. Submitted by Principal investigator, Ravi Kant,Ph.D Scholar, under the guidance of Dr. Meenu Gupta. Professor, Deptt. of Radiation Oncology,CRI, HIMS, Swami Rama Himalayan University.

Dear, Dr. Ravi,

With reference to your submission letter, dated 06.02.2023, the Ethics Committee, Swami Rama Himalayan University, discussed and approved the Ph.D Synopsis entitled: **Dosimetric evaluation in carcinoma lung by intraluminal brachytheripy and correlation in phantom model.."** in its meeting held on 27/03/2023 at 10:00 AM in the Department of Pharmacology, HIMS.

Following Documents were received for the Study:
1. Performa Ph.D Synopsis

The following members were present:

Sr. No.	Name of the Member	Designation and Qualification	Representation as per Schedule Y	Gender	Affiliation with the Institution
1.	Prof. K.C. Mishra	Chairman MBBS, MD, MAMS	DRME (Pb.) & Ex. Principal	M	No
2.	Mr. G.N.S. Gurudutt	Member M.A,. M.phil.	Social Scientist	M	No
3.	Mr. Arun Kundra	Member M.A. , L.L.B	Practicing Advocate	M	No
4.	Mr. Sagar Manwal	Member Gram Pradhan, Jolly Grant	Community Representative	M	No
5.	Prof. Mushtaq Ammed	Member MBBS, MD (Radiotherapy)	Clinician Professor, Deptt. of Radiotherapy	M	Yes
6.	Prof. Jaynati Semwal	Member MBBS,MD, (Community Medicine	Professor Deptt. of Community Medicine	F	Yes
7.	Dr. Aksh Dubey	Member MBBS,MD, (Anatomy)	Assoc. Professor, Deptt. of Anatomy	M	Yes
8.	Prof. D.C. Dhasmana	Member Secretary, MBBS,MD(Pharmacology)	Pharmacologist	M	Yes

This is to confirm that only members, who were independent of the Investigator of the study, have voted and provided opinion on the study.

The Ethics Committee, Swami Rama Himalayan University, has no objection to the conduct of the study in the present form, as per the submitted protocol, subject to the statuary provisions and permissions, as necessary, to be obtained from concerned authorities.

The Ethics committee, Swami Rama Himalayan University expects to be informed about the progress of the study, any changes in the protocol and asks to be provided a copy of the final report.

The Ethics committee, Swami Rama Himalayan University follows procedures that are in compliance with the requirements of ICH (international Conference on Harmonization) guidelines related to GCP (Good Clinical Practice) and applicable Indian regulations, revised and updated from time to time.

Dr. D.C. Dhasmana,
Member Secretary, Ethics Committee

Dr. D.C. Dhasmana
Deptt. of Pharmacology
& Member Secretary
Ethics Committee
SRH University
Ram Nagar Dehra Dun-24

Annexure-II A

Published Original Research Paper

DOI: 10.7860/JCDR/2023/63600.17885

Original Article

Oncology Section

Dosimetric and Volumetric Analysis in Endobronchial Brachytherapy in Lung Carcinoma: A Cross-sectional Study

RAVI KANT[1], MEENU GUPTA[2], JYOTI BISHT[3], VIPUL NAUTIYAL[4], VINEY KUMAR[5], RISHABH DOBHAL[6], MUSHTAQ AHMAD[7], SUNIL SAINI[8]

ABSTRACT

Introduction: High Dose Rate (HDR) brachytherapy plays an important role in the treatment of lung carcinoma. The treatment of lung carcinoma with Endobronchial Brachytherapy Treatment (EBBT) is delivered with three fractions and the effect of EBBT on the Target Volume (TV) after delivering the three fractions in the lung carcinoma needs to be assessed. The TV is covered with the prescribed dose and Organs At Risk (OARs) doses are evaluated.

Aim: To assess the doses to OAR nearby the tumour and analyse the effect of the TV, tumour location, and site on the doses to OARs in EBBT in lung carcinoma.

Materials and Methods: A cross-sectional study was conducted in the Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University Dehradun, Uttarakhand, India, from January 2018 to December 2020. Thirty patients with lung carcinoma were included in dosimetric and volumetric assessments. A flexible lumencare catheter was inserted into the bronchial lesion. Computed Tomography (CT) scan was acquired and exported to Treatment Planning System (TPS) through Digital Imaging and Communications in Medicine (DICOM) networking system. An optimised treatment plan was generated. The TV and OARs were delineated on the CT scan of the patient. A total of three EBBT sessions were given with a 7 Gy dose per fraction and prescribed the dose at 1.0 cm from the center of the catheter. Doses to OARs and the effects of TV on doses to OARs were evaluated with the help of "Dose Volume Histogram (DVH) tool" in the TPS. Thirty patients, with varying TV and site, were grouped as left lung and right lung tumour lesions and also grouped as TV <22 cc and TV >22 cc for the analysis purpose in this study. The data was entered in Microsoft Office Excel 2007 and analysed in Statistical Package for the Social Sciences (SPSS) version 22.0 statistical analysis software (IBM Corp., Armonk, N.Y., USA) tool.

Results: The mean doses to OARs in 1st, 2nd and 3rd EBBT sessions were within their tolerance limit. The mean dose difference between left and right lung tumour site were analysed and found mainly the mean dose to oesophagus and maximum dose to oesophagus, contralateral lung, left coronary artery and descending aorta were significantly higher in left lung compared to right lung with p-value 0.015, 0.027, 0.001, 0.007 and 0.001, respectively. The maximum dose to the contralateral lung and spinal cord were significantly higher in middle-lower bronchial lesion with p-value 0.024 and 0.023, respectively. The mean dose difference between left and right lung tumour volume for TV <22 cc and TV>22 cc was analysed and found mainly for the group TV>22 cc the mean dose to oesophagus and maximum dose to oesophagus, Heart, contralateral lung, left coronary artery and descending aorta were significantly higher in the left lung compared to right lung with p-value 0.002, 0.008, 0.027, 0.003, 0.006 and 0.001, respectively whereas in the TV<22 cc group only the contralateral lung max dose was significantly higher in left lung compared to right lung with p-value 0.046.

Conclusion: The OARs doses were increased significantly in left lung compared to right lung carcinoma. The TV was large in the middle-lower bronchial region, therefore, the doses were found higher, and TV in the lower bronchial region is less so the dose was less.

Keywords: Bronchial lesion, Dose volume histogram, Fraction, Organ at risk, Target volume

INTRODUCTION

The HDR brachytherapy plays an important role in the treatment of lung carcinoma. A radioactive source Ir-192 provides a very high dose to the tumour and lower dose to surrounding structures by the dosimetric characteristics. The dose measured at any point decreases with increasing the distance between the source and point of measurement due to rapid dose fall off property. The radioactive source is accurately transported from the remote after loading system to the catheter/applicator in the tumour site with high accuracy in brachytherapy [1]. In the treatment of lung carcinoma, EBBT is well-established modality with high response rates [2,3]. EBBT is used in the treatment of bronchogenic carcinoma curatively. EBBT is used either alone or in combination with external beam radiotherapy [4,5]. A worldwide American Brachytherapy Society (ABS) recommends the guidelines for brachytherapy treatment. The ABS suggests that when brachytherapy is used for the palliation, as a sole modality for treatment, the dose fractionation schedule is 7.5 Gy per fraction for three fractions, 10 Gy per fraction for two fractions or 6 Gy per fraction for four fractions with one week gap in between the fractions [6]. The dose must be prescribed at 1cm radius from the catheter center in EBBT for the treatment length [7]. One another dose prescription method is to the bronchial mucosa segment within the target after measuring the tracheobronchial airway [8]. There may be under dose at the proximal end and overdose at the distal end of the mucosa on the target. In the latter method where the dose prescribed at mucosa then a condition of overdose arises, if catheter is in close contact with the mucosa. On the plain radiograph, the detailed dosimetric analysis is not possible. Hence, important dosimetric information is collected with the CT scan in brachytherapy [9]. EBBT planning in the lung carcinoma is performed on the CT data set of the patient with the lumencare 6F catheter inserted in the bronchus where the radiation dose to be given. The radiation dose to the tumour is delivered in

the HDR after loading brachytherapy machine (microselectron HDR) with Ir-192 radioactive source. The TV is covered with the prescribed dose and OARs doses are evaluated at the time of plan approval in TPS. The brachytherapy treatment procedure time can be reduced by starting the treatment without any delay if standard doses and lengths are used. The treatment planning time is feasibly reduced when one catheter is used with minimal curvature in the irradiated area and by applying precalculated standard treatment plans for 3-10 cm tumour length with the 5-10 Gy dose prescribed at 1 cm from the source centre with equal dwell times [10].

Present study is novel as there is no literature published in this field of knowledge as authors carry out an exhaustive literature search in this area. The present study of volumetric and dosimetric evaluation in EBBT was done to analyse the effect of tumour location in the bronchus, tumour site, and TV on OARs doses in EBBT treatment.

MATERIALS AND METHODS

This was a cross-sectional study conducted in the Radiation Oncology Department Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University Dehradun, Uttarakhand, India, on patients of lung carcinoma from January 2018 to December 2020. Ethical Clearance from the Institutional Ethical Committee (IEC) with approval number SRHU/HIMS/E-1/2023/54 was obtained.

Inclusion criteria: Patients with carcinoma of the lung with the endobronchial tumour in the primary and secondary bronchus were included in the study.

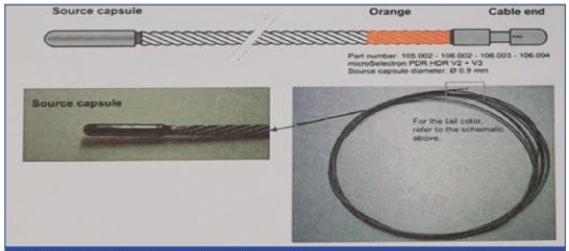
Exclusion criteria: Patients with tumour in the plural and peripheral part of the lung other than primary and secondary bronchus were excluded from the study.

Patient selection: Purposive and convenient sampling was done due to the limitation of the patients. Total 30 patients with lung carcinoma were equally distributed in two groups for left and right lung carcinoma. The two groups were further divided into two subgroups, in each main group for tumour location in the lower and middle bronchus region where again almost equal numbers of patients were included. In the subgroups, eight patients were lower bronchus lesions and seven patients were middle bronchus lesions in either side of the lung carcinoma. As per the TV, 30 patients with different TV were classified into two groups TV <22 cc and TV >22 cc.

Endobronchial Brachytherapy (EBBT): Bronchoscopy was performed prior to EBBT to evaluate the tumour location, size, and obstruction under local anaesthesia. The bronchoscopic findings were used to determine the TV. The upper and lower margin of the TV was taken very carefully. In a completely obstructive lesion, the distal margin through endoscopy was not possible. The lumencare 6 French (6F) catheter was inserted through the brush channel of the bronchoscope into the tumour. A dummy source X-ray marker was positioned in the catheter which was inserted into the bronchus to visualise the catheter in the CT images. A source position simulator instrument tool was used to determine the length of the catheter and check for any obstruction in the catheter prior to the CT scan. The study was based on the CT scan data of the patient so there were no premedication/ anaesthetic procedures required.

Treatment planning: The patient CT scan was obtained with 2-3 mm axial CT slice with a dummy source and exported to the TPS (Oncentra Master Plan V3.3; Nucletron Pvt., Ltd.,) through "DICOM" local area networking system for treatment planning. The length, lateral and vertical extension of the tumour volume and OARs was delineated by the radiation oncologists on the CT data set. The accurate TV definition and volumetric dose information were possible with CT scan-based planning which can improve the brachytherapy therapeutic ratio [9].

The catheter was reconstructed by medical physicists. The dwell positions were selected to cover the endobronchial tumour volume and the additional margin was taken on distal and proximal ends. The dose per fraction was used 7 Gy prescribed at 1 cm from centre of the catheter for treatment length including 2 cm margin at both the ends as per the ABS guidelines for brachytherapy treatment in lung carcinoma [6]. The optimised EBBT plan was exported to the microselectron HDR V3 remote after loading unit (Nucletron Pvt., Ltd.,) for treatment execution. The Ir-192 HDR source has a source capsule length 4.5 mm and diameter of 0.9 mm in the HDR unit [Table/Fig-1] [11].



[Table/Fig-1]: High-dose-rate 192Ir brachytherapy source capsule design.

Three EBBT sessions were given to each patient and three CT scan set of every patient taken for the treatment purpose. The first session, second session and third session CT data set was named as $CT_{1\#}$, $CT_{2\#}$ and $CT_{3\#}$ in each patient, respectively. The TV and OAR were delineated in the CT scan of the patient by radiation oncologists. The dosimetric and volumetric analysis was performed on all the patient's plans. The total doses to OARs in three EBBT session and effect of TV, tumour site and tumour location on OARs doses were recorded from the DVH and detail table tool from the plan analysis window in TPS in each patient.

STATISTICAL ANALYSIS

Interpretation and analysis of the results obtained were carried out using SPSS statistics version 22.0 software (IBM Corp., Armonk, N.Y., USA) and MS Excel spreadsheets. The means of the doses were compared by the parametric independent-samples t-test and it was statistically significant by $p<0.05$.

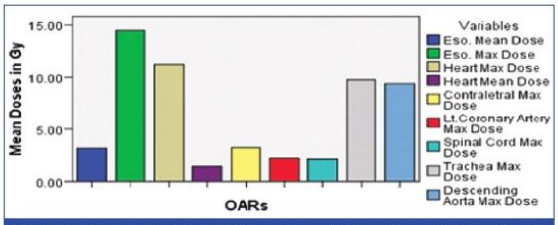
RESULTS

Thirty patients of lung carcinoma with mean age 63.1 years with male (N=28) to female (N=2) ratio of 14:1. Ninety EBBT sessions of 30 lung carcinoma patients were assessed for dosimetric as well as volumetric evaluation after the completion of treatment. The dose and volume parameters in the first session of brachytherapy were made the reference or base values for assessment of effects after second and third sessions of brachytherapy in each patient.

Dosimetric analysis: The average maximum doses to oesophagus, heart, contralateral lung, left coronary artery, spinal cord, trachea and descending aorta were 14.48, 11.22, 3.21, 2.22, 2.14, 9.77 and 9.4 Gy and average of the mean dose to oesophagus and heart were 3.18 and 1.42 Gy in three EBBT sessions, respectively [Table/Fig-2].

The mean dose difference between left and right lung tumour site were analysed, the mean dose to the oesophagus and maximum dose to the oesophagus, contra-lateral lung, Lt. coronary artery and descending aorta were significantly higher in the left lung compared to right lung, respectively [Table/Fig-3].

The maximum dose to the contra-lateral lung and spinal cord were significantly higher in middle-lower bronchial lesion with p-value 0.024 and 0.023, respectively [Table/Fig-4].



[Table/Fig-2]: Graph showing OARs mean doses received in three EBBT sessions.

S. No.	Organs At Risk (OAR)	Left lung mean dose (Gy)	Right lung mean dose (Gy)	Mean difference	p-value*
1	Oesophagus mean dose	3.7±1.65	2.57±0.70	1.20000	**0.015**
2	Oesophagus max dose	20.6±20.01	8.3±4.2	12.32333	**0.027**
3	Heart max dose	11.36±3.01	11.07±3.65	0.28800	0.816
4	Heart mean dose	1.50±0.33	1.33±0.60	0.17200	0.340
5	Contralateral lung max dose	4.61±2.75	1.80±1.31	2.81067	**0.001**
6	Lt. coronary artery max dose	2.71±1.20	1.70±0.56	1.00933	**0.007**
7	Spinal cord max dose	2.16±0.81	2.10±0.86	0.06333	0.839
8	Trachea max dose	10.29±4.18	9.23±4.70	1.06800	0.517
9	Descending aorta max dose	13.33±5.60	5.45±4.93	7.88533	**0.001**
10	Liver max dose	0.28±0.37	1.63±3.34	-1.35400	0.130
11	Kidney max dose	0.018±0.069	0.020±0.077	-0.00200	0.941

[Table/Fig-3]: Effect of tumour site on the doses to the Organs At Risk (OAR) in the EBBT sessions.
*Independent sample t-test was used for statistical analysis; p-value <0.05 is statistically significant

S. No.	Organs At Risk (OAR)	Lower region mean dose (Gy)	Middle-lower region mean dose (Gy)	Mean difference	p-value*
1	Oesophagus mean dose	3.17±1.70	3.18±0.98	-0.01018	0.984
2	Oesophagus max dose	9.94±5.57	19.65±21.17	-9.70857	0.088
3	Heart max dose	11.26±3.47	11.17±3.20	0.08991	0.942
4	Heart mean dose	1.43±0.59	1.40±0.33	0.02661	0.884
5	Contralateral lung max dose	2.24±1.46	4.31±3.10	-2.07357	**0.024**
6	Lt. coronary artery max dose	2.01±1.46	2.44±1.37	-0.42768	0.277
7	Spinal cord max dose	1.82±0.68	2.49±0.85	-0.67643	**0.023**
8	Trachea max dose	8.72±3.48	10.95±5.14	-2.23723	0.170
9	Descending aorta max dose	9.19±6.78	9.63±6.53	-0.43750	0.859
10	Liver max dose	0.45±0.94	1.53±3.39	-1.07438	0.235
11	Kidney max dose	0.00±0.00	0.04±0.10	-0.04071	0.126

[Table/Fig-4]: Effect of tumour location on the doses to the Organs At Risk (OAR) in the EBBT sessions.
*Independent sample t-test was used for statistical analysis; p-value <0.05 is statistically significant

Volumetric analysis: The volumetric analysis was performed on all the patients where the TV obtained from the TPS. The TV of 30 patients obtained from the TPS was classified in two groups as TV <22 cc and TV >22 cc for the analysis purpose and introduce a concept where tumour volume effect the doses to OAR in left and right lung lesion. In the two groups TV <22 cc and TV >22 cc, the patient's frequency was 14 and 16, respectively. The OARs doses were compared among these two TV groups for left and right-side lung tumour lesions. It was found that the OARs doses vary significantly in the group TV>22 cc among left and right-side lung tumour lesions whereas in the group TV<22 cc contralateral Lung max dose was found significant whereas rest of the OARs no significant variation found in left and right-side lung tumour lesion [Table/Fig-5,6].

S. No.	Organs At Risk (OAR)	Mean±SD (Doses in Gy)		Mean difference	p-value*
		Left lung	Right lung		
1	Oesophagus mean dose	3.43±1.69	2.33±1.13	-1.6229167	**0.002**
2	Oesophagus max dose	15.70±20.86	7.00±9.82	-11.7329167	**0.008**
3	Heart max dose	11.04±3.41	10.89±3.97	-0.9029167	0.671
4	Heart mean dose	1.54±0.62	1.25±0.39	-0.4179167	**0.027**
5	Contralateral lung max dose	3.32±3.21	1.57±1.72	-2.2716667	**0.003**
6	Lt. coronary artery max dose	3.17±0.58	1.67±1.47	-1.9716667	**0.006**
7	Spinal cord max dose	2.07±0.62	2.33±0.97	-0.2175000	0.638
8	Trachea max dose	8.78±3.29	6.30±4.52	-2.6304167	0.253
9	Descending aorta max dose	13.77±5.76	2.92±6.54	-13.1820833	**0.001**
10	Liver max dose	0.36±0.96	2.38±041	0.7058333	0.291
11	Kidney max dose	0.03±0.08	00.00±0.09	-0.04500	0.264

[Table/Fig-5]: Effect of tumour volume TV >22 cc on the doses to the Organs At Risk (OAR) in the EBBT sessions.
*Independent sample t-test was used for statistical analysis; p-value <0.05 is statistically significant

The sum of OARs doses in first, second and third session of brachytherapy was calculated and compared the doses in different groups which were made as per the tumour lesion site, location and TV. The results showed that the tumour location in the lungs, tumour site in left and right lung and TV >22 cc and TV <22 cc affect the doses to OARs in brachytherapy treatment of lung carcinoma patients.

DISCUSSION

As per the literature many studies are found related to the clinical point of view and on the outcome of the brachytherapy treatment on the relief of symptoms and improved quality of life of the patient post-treatment [10]. As the work related to this study is not performed earlier so no data is available to compare the dosimetric and volumetric findings. Dhillon S et al., observed the endoscopic response at one-month post-treatment in 84% of patients and more than 50% endobronchial component reduction in 15 patients [12]. In this situation, immediate priority is given to remove the blockage in the bronchus to clear the airway path of the patient [13,14]. Gustafson G et al., reported that the degree of obstruction was reduced by around 50% or greater in 64% of their patients [15]. This reduction in the obstruction can be related with the tumour volume, which affects directly the doses to the OAR in three consecutive EBBT sessions in the included patients. As the OAR doses in the other sites like carcinoma cervix and oesophagus were analysed by the authors whereas, in the EBBT, the dosimetric and volumetric analysis was not found in the literature available.

Singh DP et al., prescribed the dose at 0.8 cm distance instead of 1 cm distance from the centre of the catheter by measuring

S. No.	OARs	Mean±SD (Doses in Gy)		Mean difference	p-value*
		Left lung	Right lung		
1	Oesophagus mean dose	4.16±2.13	2.84±0.81	-0.7574603	0.364
2	Oesophagus max dose	26.27±27.43	9.81±5.71	-11.8620635	0.242
3	Heart max dose	11.72±1.56	11.28±4.76	0.3914286	0.804
4	Heart mean dose	1.46±0.25	1.43±0.87	0.0450794	0.884
5	Contralateral lung max dose	6.09±0.37	2.07±1.86	-3.0736508	**0.046**
6	Lt. coronary artery max dose	2.19±0.49	1.74±0.61	-0.3088889	0.225
7	Spinal cord max dose	2.27±0.68	1.84±0.52	0.0493651	0.725
8	Trachea max dose	12.03±3.23	12.57±3.58	0.9614286	0.677
9	Descending aorta max dose	12.83±4.77	8.34±6.12	-3.1242857	0.277
10	Liver max dose	0.18±0.32	0.77±3.31	1.9987302	0.227
11	Kidney max dose	0.00±0.00	0.04±0.11	0.0428571	0.271

[Table/Fig-6]: Effect of tumour volume TV <22 cc on the doses to the Organs At Risk (OAR) in the EBBT sessions.
*Independent sample t-test was used for statistical analysis; p-value <0.05 is statistically significant

the distance between the mucosa and catheter in the CT scan of the patient. The dose coverage to the endobronchial lesion was adequate in this [16]. The normal transfer tube used in the EBBT placed eccentrically in the bronchial lumen for irradiation leads to a high dose on the bronchial mucosa. Omori K et al., developed an applicator with two wings that open at the radiation delivery location and maintain the source in the centre of the lumen to minimise the radiation dose to the bronchial mucosa. They reported that by using this applicator the haemoptysis and bronchial stenosis were less in EBBT [17]. Sur R et al., did a randomised trial study and found that there was a moderate improvement in the relief of symptoms by combining the two treatment modalities like EBBT and EBRT but the improvement was not statistically significant [18].

Brachytherapy can be a choice of treatment in lung carcinoma depending upon the location of the tumour lesion. The tumour volume affects the doses to the OAR and tumour volume coverage with prescribed dose. Large tumour volume showed the increased doses to OARs. The strength of the study was to explore the factors affecting the doses to the OAR in lung carcinoma brachytherapy. Results of this study can be helpful in the selection of the patient for brachytherapy treatment. This treatment option is fast to perform, not very expensive, and can be performed on an outpatient basis.

On the basis of observed findings, it can be stated that EBBT provides effective palliative treatment and should be recommended to patients with endobronchial tumour lesions.

Limitation(s)

The limitation of the study was relatively small cohort/sample size because the EBBT technique is not regularly performed and the patients with tumour located only in the major bronchi were included in the study because the patient selection for EBBT is very important. The study included the doses to OAR calculated by the TPS only which were not validated in the study by any other experimental dosimetric method in the lung carcinoma EBBT technique.

CONCLUSION(S)

The OARs doses were higher for a large-volume tumour in the middle-lower region than small volume tumour in the lower region in the bronchus whereas, the OAR tolerance dose limit was not exceeded. The OARs doses were higher in left lung carcinoma than in right lung carcinoma patients. The effect of TV on the OARs doses was significant for TV>22 cc and contralateral lung max dose was found significant whereas rest of the OARs no significant variation found for TV<22 cc in left and right-side lung lesions. Hence, the EBBT is a very effective treatment modality in lung carcinoma with the best selection of the patient considering the tumour location and site to achieve an optimised plan with good quality of life.

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PARTICULARS OF CONTRIBUTORS:
1. Ph.D. Research Scholar (Medical Physics), Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.
2. Professor, Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.
3. Assistant Professor, Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.
4. Professor, Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.
5. Assistant Professor, Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.
6. Lecturer, Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.
7. Professor, Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.
8. Professor, Department of Surgical Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Mr. Ravi Kant,
Ph.D. Research Scholar (Medical Physics), Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Jolly Grant Doiwala, Dehradun-248016, Uttarakhand, India.
E-mail: ravikantphy@gmail.com

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Annexure-II B

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Review Article

A review article on the dosimetry in intraluminal HDR brachytherapy of lung carcinoma

ABSTRACT

Lung cancer is one of the most common cancers in the world. Intraluminal brachytherapy (BT) is one of the most adopted treatment modalities for lung malignancies with Ir-192 source in radiotherapy. In intraluminal BT, treatment delivery is required to be very accurate and precise with respect to the plan created in the treatment planning system (TPS). The BT dosimetry is necessary for better treatment outcomes. Therefore in this review article, some relevant studies were identified and analyzed for dosimetric outcomes in intraluminal BT in lung malignancies. The dosimetry in BT for plan verification is not presently in practice, which needs to be performed to check the variation between the planned and measured doses. The necessary dosimetric work done by the various researchers in intraluminal BT such as the Monte Carlo CYLTRAN code was used to calculate and measure the dose rate in any medium. Anthropomorphic phantom was used to measure doses at some distance from the source with Thermo luminescence dosimeters (TLDs). The dosimetric influence of air passage in the bronchus was evaluated with the GEANT4 Monte Carlo method. A pinpoint chamber was used to measure and quantify the impact of inhomogeneity in wax phantom for the Ir-192 source. The Gafchromic films and Monte Carlo methods were used to find the phantom and heterogeneities, which were found to underestimate the dose for the lungs and overestimated for the bones in TPS. The exact tool to quantify the variation in planned and delivered doses should be cost-effective and easy to use possibly with tissue equivalent phantoms and Gafchromic films in lung malignancies treatment.

KEY WORDS: High dose rate brachytherapy, thermoluminescence dosimeters, treatment planning system

Ravi Kant, Meenu Gupta, Jyoti Bisht, Vipul Nautiyal, Viney Kumar, Rishabh Dobhal, Mushtaq Ahmed, Sunil Saini

Department of Radiation Oncology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Dehradun, Uttarakhand, India

For correspondence: Mr. Ravi Kant, Assistant Professor [Medical Physics], Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, P.O. Jolly Grant, Doiwala, Dehradun - 248 140, Uttarakhand, India. E-mail: ravikantphy@gmail.com

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INTRODUCTION

Worldwide, one of the most common cancers is lung cancer (2.09 million cases) and the most common cause of death is lung cancer (1.76 million deaths). In India, each year 63,000 (approximately) new lung carcinoma cases are reported.[1] The main risk factors worldwide for lung carcinoma are use of tobacco, alcohol, an unhealthy diet, and physical inactivity. The cancer burden can be reduced by avoiding the risk factors and by executing the strategies, which exist for prevention. If cancer is diagnosed early and treated effectively, many cancers have a high cure rate with a high chance.

The treatment of cancer depends upon the type of cancer and stage of the disease as each subtype needs a specific treatment regimen, which includes surgery, radiation therapy, and chemotherapy. The primary goal is to cure carcinoma and improve the quality of life of cancer patients, which can be attained by using the optimal modality of treatment as a single modality or in combination.

Radiation therapy is one of the principal modalities used for the treatment of cancer as a single modality or in combination with other available modalities of treatment. Radiation therapy is delivered by two methods, external beam radiation therapy (EBRT), and brachytherapy (BT). The EBRT is the treatment of a tumor from some distance and BT is the precise placement of the small encapsulated radioactive source directly inside or in close proximity to the tumor. The advantage of using BT is to deliver the maximum localized dose to the tumor and spare healthy tissues, which is the main objective of radiation therapy.[2]

In lung cancer, radiation therapy is used in small cell carcinoma with curative intent in a combination with chemotherapy. In non-small cell carcinoma,

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lung surgery is the main type of treatment, whereas radiation therapy is used as an adjuvant or for palliation.

Radiation therapy used in lung carcinoma is mainly by EBRT; however, there are indications where radiation therapy is used as BT.

The "American Brachytherapy Society" (ABS) issued guidelines for BT in lung carcinoma. ABS recommends that patients with hemoptysis and postobstructive pneumonitis can be considered for palliative endobronchial (EB) BT.[3] The tumors involved the lumen, which compresses the bronchus/trachea and leads to cough and breath shortness with hemoptysis. EB BT generally gives fast palliation of blockage than external beam radiation therapy.

The ABS recommends that EB BT is performed via trans-nasal technique with the help of a flexible fiberoptic bronchoscope under conscious sedation administered by a well-trained person. A guidewire is used to visualize the catheter under fluoroscopy because EB lesion is visualized through bronchoscopy but not by fluoroscopy. Markings on a catheter define its location relative to the tumor and help in treatment planning. The catheter insertion is completed with the help of bronchoscopy. The ABS suggests that 7.5 Gy/fraction per week for 3 weeks, 10 Gy/fraction per week for 2 weeks, or 6 Gy/fraction per week for 4 weeks when HDR BT is used for palliation.

The dose prescription point in EB High Dose Rate (HDR) BT can be selected in two ways, one is at 1.0 cm from the catheter center and the other one is at various distances around the catheter center, which depends upon the trachea or bronchial diameter at that level. To treat the tumor adequately, a margin of 1 cm to 2 cm is recommended at each end of the catheter. The optimized dose distribution is completed in the treatment planning system (TPS) dedicated to HDR BT.

The accurate and reliable quantification of BT dose distributions is of vital importance in clinical treatment planning. The distribution of dose around the radioactive source used in BT is classified by energy spectrum with sharp dose gradients varying rapidly about the source using the depth in water. The doses around BT sources can be determined by experimental and Monte Carlo methods. Accurately placement of the detector is important for radiation dose measurement and the measured signal is proportional to the relative/absolute dose in the absence of a detector in the medium. The detectors used in this application include small TLD dosimeters, Gafchromic film, and an ionization chamber.

As far as the suitability of a dosimeter is concerned, TLD has already been established as a detector offering the best compromise between small size, sensitivity, flat energy response, and ease of accurate positioning. The American Association of Physicists in Medicine (AAPM) also recommends that LiF-based TLD be used for dose verification measurements for BT applications.[4] However, the method based on TLD is cumbersome and related to volume averaging, positioning errors, and self-attenuation factors. The ionization chamber is capable of real-time dosimetry and does not fulfill the requirement of resolution because of the finite physical dimension of the detector. In addition, the positioning of the ionization chamber with respect to the BT source is also labor-intensive and time-consuming. In recent times, radiochromic films such as Gafchromic External Beam Therapy (EBT) series films are in use for experimental dosimetry in BT.[5-7] EBT films provide a nonlinear dose-response. Gafchromic EBT3 film is the most recent version of the EBT series films. EBT3 film exhibits high resolution, which makes it appropriate for measuring rapidly falling doses around BT sources. The film is nearly tissue equivalent and possesses low energy dependency within the range of calibration. In addition, dosimetry with Gafchromic film is a user-friendly and cost-effective method, which is convenient to be used even in a busy clinical setup.

An important part of BT treatment planning is the calculation of absorbed dose distribution in a patient body. In an attempt to minimize the large variation of dosimetric information determined by various investigators, the AAPM Task Group 43 (TG 43/TG43U1) has recommended a formalism for determining the distribution of dose rate in water medium about a single sealed source used in BT.[4] The algorithm of dose calculation in most BT TPS is based on this formalism, which assumes a homogeneous water equivalent medium around the source. This difference between the planned and the actual condition includes the effects of patient heterogeneities, applicator attenuation, and altered scatter conditions. The inaccurate treatment causes late complications and significantly reduces the quality of life. Thus it is important to quantify the difference between TPS calculated and the actual dose delivered.[8]

It is evident that treatment outcome entirely depends on the accuracy with which the tumor has been delineated, and the precision of treatment planning using radiation dosimetry. The advanced imaging modality such as multi-slice CT scanners, functional magnetic resonance imaging (MRI), and Positron Emission Tomography with Computed Tomography (PET-CT) provided a newer approach to delineating target volume and Organs At Risk (OARs) for accurate dose delivery. EB BT is useful in lung cancer patients with residual or recurrent disease as a salvage treatment, whereas other treatments such as chemotherapy, surgery, and external beam radiotherapy failed.[9] EB BT can be given as a definitive treatment for EB metastasis after surgery for non-small cell lung cancer [NSCLC].[10] In the condition where the patient is not willing for surgery or stereotactic body irradiation therapy (SBRT) treatment then EB HDR BT can be given safely for curative intent with excellent long-term outcome yield.[11]

The use of EB BT increases after the development of high activity Iridium-192 source in remote afterloading HDR

machine along with the use of bronchoscope (fiberoptic). The CONSORT statement is shown in Table 1 and the flow diagram of the literature search process is shown in Figure 1.

LITERATURE REVIEW

Meigooni *et al.*[12] did a study to validate the assumption of a uniform, homogeneous medium around the implanted source equivalent to water. They used the Monte Carlo (MC) to calculate and measure dose rates with a symmetry-like cylinder in homogeneous and heterogeneous media for points along the traverse axis of the Pd-103, I-125, and Am-241 BT sources. They made a solid water phantom for a single-source implant having a cylindrical shell of 1 or 2 cm thick replaced by a polystyrene shell for irradiation. They used the CYLTRAN code of the Monte Carlo integrated series. He found that the dose rate measured beyond the 2 cm thick polystyrene heterogeneity was about 103%, 55%, and 10% greater for the Pd-103, I-125, and Am-241 sources, respectively, than the dose rate measured in a phantom of solid water, which is homogeneous. Hence, it is observed that if the heterogeneity size increase and energy decrease, the dose rate varies sharply. As per their study, it is shown that formalism on an easy calculation of the dose was developed to guess, with cylindrical symmetry, dose rate in phantom with heterogeneity.

Patel *et al.*[13] did a study "to achieve dose uniformity for intraluminal implants by assessment of dose distributions for single catheter generated using various combinations of source stopping spacing and optimization mode." They used an HDR Ir-192 source for the intraluminal BT to produce the distribution of dose in one catheter with a straight position and fixed length. They used 0.2, 0.5, 1.0, 1.4, 2.0, 2.5, 3.0, and 3.3 cm combinations of spacing in the source position and mode of optimization. They used three modes of optimization to evaluate the distribution of doses to calculate the time of stopping in the catheter. To find out the distribution of the dose, they used three main parameters such as statistical analysis of doses to reference points, the region covered by the dose–volume histogram, and the ratio of the non-uniformity dose. The result of the study showed that to identify the preferred best possible consistent dose distribution, there was no match available between the optimized mode and spacing of the source position, though a relatively higher consistent distribution of the dose is found for the source spacing with 0.2 cm short and 1.5 to 2.0 cm longer conditions. Iterative correction optimization mode used in intraluminal BT for a single catheter was found to be suitable.

Nikoofar *et al.*[14] did a study to determine the dose of OARs (parotids, eyes, thyroid gland, trachea, sub-mandibular, spinal cord, and manubrium of the sternum in an anthropomorphic phantom in HDR BT. Radiation doses to OARs were measured in the anthropomorphic body phantom using TLDs. A target volume (TV) of around 23 cm^3 was taken in the upper thoracic cavity and the phantom was scanned in CT. After the planning, the phantom was exposed to the HDR remote after-loading machine. The doses (in cGy) were measured with TLDs calibrated for the dose range. In the areas greater than 16 cm from the target measured dose ranged from 1.65 cGy to 5.5 cGy and in nearer areas lesser than 16 cm the dose was found to high as 113 cGy. Thus the study showed in the nearer areas, the surface doses and depth doses were significantly changed because of the high dose gradient and difference among plan and measured doses because of the tissue inhomogeneity.

Hiroyuki *et al.*[15] did a study to evaluate the dosimetric influence of air passage on carcinoma of the bronchus BT by TPS calculated and Monte Carlo simulation method. They analyzed patient CT data information that had gone for Intraluminal Radiation Therapy (ILRT) HDR BT to check the air passage geometry. They developed a system of measurement, which is capable to measure the exterior dose with an air cavity or without an air cavity around a catheter

Table 1: Consort statement

Section/topic	Checklist item
Title	The title is clearly mentioned for the review article
Abstract	Unstructured abstract with a summary of the review article present
Introduction	Scientific background and explanation of rationale present
Literature review	The literature review explains the studies included in the review article and also explained the methodology used in the studies reviewed
Results and conclusion	Explain the result and outcome of the studies reviewed in this review article

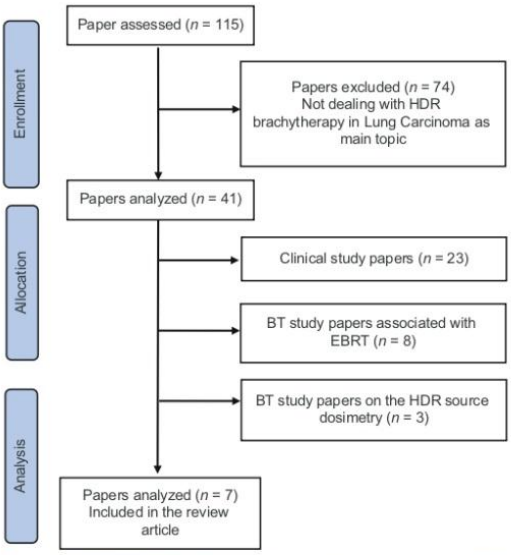

Figure 1: CONSORT flow diagram showing literature search for HDR intraluminal brachytherapy in lung malignancies

by ionization chamber. They modeled five (five) cavities of air with radii of 0.3 cm, 0.5 cm, 0.75 cm, 1.25 cm, and 1.5 cm by cylindrical tubes around the catheter. The dosimetric effect of the air cavity was evaluated by the GEANT4 Monte Carlo code method. The dose measured in water and calculated in GEANT4 was compared, which showed a maximum overdose of 5% to 8% near the air cavity surface in maximum radii of 1.5 cm. However, they showed a minimum overdose in the region 3 cm to 5 cm from the surface of the cavity is ~1% for 0.3 cm radii. The air passage distance, size, and length of treatment effects the dosimetry overdose of 3–5% for a 0.75 cm mean radii were found for the bronchus carcinoma ILRT BT depending upon the dose calculation in TPS and water. This research work showed the requirement for the development inaccuracy of dose calculation in ILRT for carcinoma bronchus.

Barlanka *et al.*[16] did a study to find the correction of tissue inhomogeneity for HDR Ir-192 source in HDR BT. They used a 0.015 mL ion chamber to measure and quantify the inhomogeneity's impact caused by different tissues. Ir-192 HDR BT source and wax phantom were used for the measurement of heterogeneities. The dose reduction caused by tissue inhomogeneity was measured as the dose with inhomogeneity divided by the dose for different distances with the homogeneous medium. The result was that different tissue attenuate differently maximum with bone and minimum for lung attenuation values showed by tissues. The result showed that at short distances, inhomogeneity was more than that at larger distances.

Akbar and Daryoush *et al.*[17] did a theoretical analysis to find the effect of dimensions of phantom and heterogeneities of tissue on dose distribution in interstitial BT. They used Gafchromic film for dosimetric measurement and Monte Carlo simulation for Ir-192 HDR source. The result of their study was 8.2% dose underestimated for lungs and 9% overestimated for bones in the TPS system. The thickness and distance from the source affect the above value. Therefore, TPS cannot include the effect of tissue heterogeneity on dose distribution in BT.

Chang *et al.*[18] performed a study on the "evaluation of dosimetric effect and treatment time by plan parameters for EB BT". They analyzed the dose distribution and treatment time by changing the position step size of the dwell position in the EB BT. In the treatment plan, they used a catheter of intraluminal and a phantom of solid water to generate a plan for 3, 5, 7, and 10 cm length of treatment with step sizes of the source position 2.5, 5, and 10 mm for each length of treatment. They set three reference points 1cm away from center of the catheter for uniform dose distribution. To study the dosimetric effect, a volumetric dose distribution was calculated. They estimated the total radiation delivery time and total dwell time, which increased with step size position. Thus, they concluded that the EB BT with a 2.5 mm step size position can be used to reduce the total treatment time.

CONCLUSION

The intraluminal BT is beneficial to patients with lung carcinoma where the lesion is in the primary and secondary bronchus. The doses received by the target volume and organ at risk are checked in the TPS and which is to be cross verified at the machine when actual treatment is executed. The doses calculated in the treatment planning system are without the inhomogeneity correction as the TPS is based on the TG 43/TG43U1 calculation formalism. To study the variation in TPS planned and actual dose delivered at the treatment machine, there should be a tool with the institute to quantify the variation to be considered while planning an intraluminal BT treatment plan on a patient. Once it is clear to us that how much variation is in the planned and delivered radiation doses, this can be considered in the patient planning. Also, the dose distribution uniformity around the BT source plays a vital role, whereas the target volume is inhomogeneous tissue, especially in lung carcinoma where the air is present, although BT has an advantage over external beam radiotherapy with rapid dose fall-off by following inverse square law.

The dosimetry in intraluminal BT is performed by some researchers such as the use of Monte Carlo CYLTRAN code to calculate and measure dose rate in heterogeneous and homogeneous media and anthropomorphic phantom to measure doses at large and small distances from the source with TLDs. The dosimetric influence of air passage was evaluated by ion chamber on bronchus BT by TPS calculated and GEANT4 Monte Carlo method. To measure and quantify the impact of inhomogeneity in wax phantom for Ir-192 source, a pinpoint chamber was used. The effect of phantom and heterogeneities was found by Gafchromic films and the Monte Carlo method. The dose was underestimated for the lungs and overestimated for the bones in the TPS system.

The exact tool to quantify the variation in the planned and delivered doses has to be cost-effective and easy to use. It can be done with the help of phantoms, Gafchromic films to check the accuracy of TPS and the dose delivery system in the treatment of lung malignancies.

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Conflicts of interest
There are no conflicts of interest.

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Annexure-III A

Certificate of ORAL Presentation in the conferences

15th & 16th
UTTARAKHAND
STATE SCIENCE AND TECHNOLOGY CONGRESS 2020-22

आज़ादी का अमृत महोत्सव

GRAPHIC ERA GROUP OF INSTITUTIONS

Certificate of Participation

This is to certify that

Mr. RAVI KANT

has actively participated in 15th Uttarakhand State Science and Technology Congress 2020-22
22nd to 24th June, 2022
and presented a research paper (Oral/Poster) entitled

DOSIMETRIC ANALYSIS OF ORGAN AT RISK DOSES AND VOLUMETRIC VARIATION IN TARGET VOLUME IN ENDOBRONCHIAL BRACHYTHERAPY TREATMENT SESSION : A PILOT STUDY

under the discipline

MEDICAL SCIENCE INCLUDING PHARMACEUTICAL SCIENCE

at Graphic Era University, Dehradun

Dr Ashutosh Mishra
Organizing Secretary - 15th USSTC
Council for Science and Technology
Uttarakhand

Dr Rajendra Dobhal, *FNASc*
Chairman - 15th USSTC
Director General
Council for Science and Technology, Uttarakhand

Annexure-III B

Certificate of POSTER Presentation in the conferences

The 21st Asia-Oceania Congress of Medical Physics

21st AOCMP

10 -12 December 2021

Venue: United International University (UIU), Dhaka, Bangladesh

This is to certify that

Ravi Kant

Has participated in the AOCMP-2021 as a poster presenter and presented the poster titled

"To Evaluate Conformity Index in ILRT and 3DCRT Plans and analyzed Volumetric Variation in The Target Volume Obtained ILRT Treatment In Carcinoma Lung Patients"

Prof Dr. Arun Chougule
President
AFOMP

Prof. Dr Golam Abu Zakaria
Patron
AOCMP 2021

Prof. Dr. Hasin Anupama Azhari
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42nd Annual Conference AMPICON 2021
Artificial Intelligence - An Emerging Trend in Medical Physics
Dr./Ms./Mr. RAVI KANT participated and delivered Poster presentation
held at 42nd Annual Conference AMPICON 2021 | Artificial Intelligence - An Emerging Trend in Medical Physics
held at NIMHANS Convention Centre, Bengaluru from 19-21 May, 2022.
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AMPICON 2021
Jerrin Amalraj
Convenor-Scientific Committee
AMPICON2021

Annexure-III C

Certificate of participation in AQUATHON 2021

SWAMI RAMA HIMALAYAN UNIVERSITY

Swami Ram Nagar, Jolly Grant, Dehradun (Uttarakhand)

Aquathon 2021

Certificate of Participation

This is to certify that

Dr./Mr./~~Ms~~.....Ravi Kant, ...H.I.MS.....has successfully participated in the "Aquathon 2021: World Water Day on March 22nd, 2021" conducted by Swami Rama Himalayan University (SRHU).

WATSAN

Registrar

Annexure-III D

Young Scientist award certificate in the UCOST 2022 conference

15th & 16th
UTTARAKHAND
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YOUNG SCIENTIST AWARD

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Rani kant

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under the discipline

MEDICAL SCIENCES INCLUDING PHARMACEUTICAL SCIENCES

in 15th Uttarakhand State Science and Technology Congress 2020-22

22nd to 24th June, 2022 at Graphic Era University, Dehradun

Dr Ashutosh Mishra
Organizing Secretary - 15th USSTC
Council for Science and Technology
Uttarakhand

Dr Rajendra Dobhal, *FNASc*
Chairman - 15th USSTC
Director General
Council for Science and Technology, Uttarakhand

Annexure-IV

PUBLISHED PATENT FROM THE PHD RESEARCH WORK

पेटेंट कार्यालय
शासकीय जर्नल

OFFICIAL JOURNAL
OF
THE PATENT OFFICE

निर्गमन सं. 20/2023	शुक्रवार	दिनांक: 19/05/2023
ISSUE NO. 20/2023	FRIDAY	DATE: 19/05/2023

पेटेंट कार्यालय का एक प्रकाशन
PUBLICATION OF THE PATENT OFFICE

INTRODUCTION

In view of the recent amendment made in the Patents Act, 1970 by the Patents (Amendment) Act, 2005 effective from 01st January 2005, the Official Journal of The Patent Office is required to be published under the Statute. This Journal is being published on weekly basis on every Friday covering the various proceedings on Patents as required according to the provision of Section 145 of the Patents Act 1970. All the enquiries on this Official Journal and other information as required by the public should be addressed to the Controller General of Patents, Designs & Trade Marks. Suggestions and comments are requested from all quarters so that the content can be enriched.

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CONTROLLER GENERAL OF PATENTS, DESIGNS & TRADE MARKS

19nd MAY, 2023

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(86) International Application No :PCT//
Filing Date :01/01/1900
(87) International Publication No : NA
(61) Patent of Addition to Application Number :NA
Filing Date :NA
(62) Divisional to Application Number :NA
Filing Date :NA

(71)**Name of Applicant :**
1)Swami Rama Himalayan University
Address of Applicant :Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand, 248016,India ---------- ----------
Name of Applicant : NA
Address of Applicant : NA
(72)**Name of Inventor :**
1)Mr. Ravi Kant
Address of Applicant :Assistant Professor [Medical Physics] Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun, Uttarakhand-248016, India ---------- ----------
2)Dr. Meenu Gupta
Address of Applicant :Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun Uttarakhand-248016, India ---------- ----------
3)Dr. Satish Uniyal
Address of Applicant :Department of Radiology, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun Uttarakhand-248016, India ---------- ----------
4)Dr. Vipul Nautiyal
Address of Applicant :Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun Uttarakhand-248016, India ---------- ----------
5)Dr. Jyoti Bisht
Address of Applicant :Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun Uttarakhand-248016, India ---------- ----------
6)Mr. Rishabh Dobhal
Address of Applicant :Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun Uttarakhand-248016, India ---------- ----------
7)Dr. Sunil Saini
Address of Applicant :Department of Surgical Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun Uttarakhand-248016, India ---------- ----------
8)Dr. Mushtaq Ahmad
Address of Applicant :Department of Radiation Oncology, Cancer Research Institute, Himalayan Institute of Medical Sciences, Swami Rama Himalayan University, Swami Ram Nagar, Jolly Grant, Dehradun Uttarakhand-248016, India ---------- ----------

(57) Abstract :
The present invention provides an Intraluminal dosimetry slab phantom that is used to verify a treatment plan created in the treatment planning computer system with the same plan actually delivered on the HDR machine for Intraluminal brachytherapy and can be utilized as a quality assurance tool in the brachytherapy of thoracic site to compare the organs at risk doses, calculated in Treatment Planning System (TPS) and measured in a tissue equivalent phantom designed for a thoracic site at different locations. The phantom includes main anatomical structures such as Left Lung, Right Lung, Heart, Esophagus, Aorta, Sternum, and spinal cord for dosimetry. The tissue equivalent materials are chosen for the structures on the basis of tissue density. The phantom is the replica of the structures located in the thoracic cavity of the patient body.

No. of Pages : 17 No. of Claims : 5

Annexure-V

PATIENT LIST FOR SECONDARY OBJECTIVE

S. No.	UHID	Gender
1	2748720	**M**
2	2851264	**M**
3	2214867	**M**
4	2037828	**M**
5	2037515	**M**
6	1917708	**M**
7	1970125	**M**
8	2157744	**M**
9	2412803	**F**
10	2265403	**M**
11	2171999	**M**
12	2159334	**M**
13	1919339	**M**
14	1928061	**M**
15	1980630	**M**
16	3061645	**M**
17	2348855	**M**
18	2097737	**M**
19	2088222	**M**
20	1968242	**M**
21	1938904	**F**
22	1918605	**M**
23	1958904	**M**
24	1733768	**M**
25	2025515	**M**
26	2218215	**M**
27	2158551	**M**
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29	2189943	**M**
30	1625589	**M**