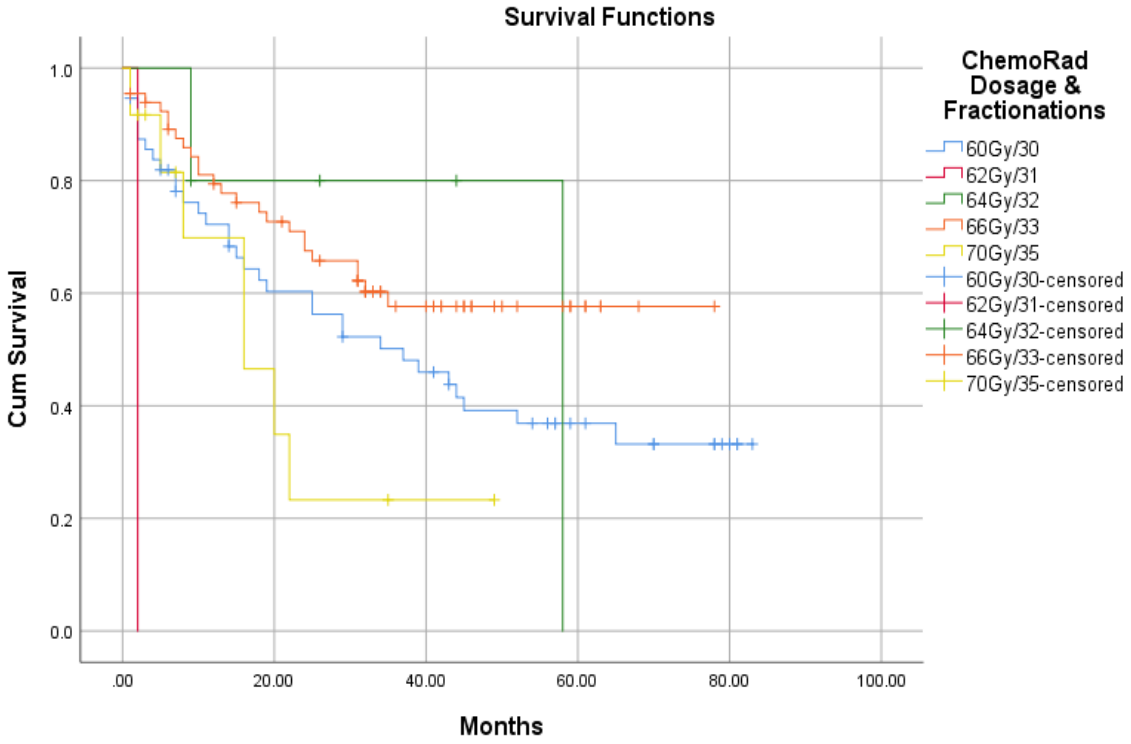
4.4 STATISTICS

Overall survival (OS) was measured from the start of diagnosis up to the time of death. Local-regional failure-free survival (LRFFS) was calculated from the beginning of treatment to the first loco-regional tumor detection. Distant metastases-free survival (DMFS) was assessed separately. Patients without tumor recurrence were censored at the last follow-up contact. Significance was defined as a $P<0.05$. Survival curves were plotted using the Kaplan–Meier method. Univariate and multivariate analysis was performed using the log-rank (Mantel–Cox) test and Cox regression respectively. Statistical analysis was performed using the SPSS Version 23 programme.

4.4.1 Overall Survival

At the time of this retrospective analysis, Fifty-two (36.4%) patients were still alive and 70 (49%) patients had died. The 2-year OS rate for the total group of patients was 36%. Only age was found to be a significant prognostic factor for overall survival in the univariate analysis. Patients between 30-49 years had a higher 2-year overall survival compared to other age groups. T category, N category, AJCC stage, and body mass index were found to be insignificant prognostic factors. The independent prognostic importance of the variables was verified by multivariate analysis of age, AJCC stage, and BMI. The log-rank p-Value of the OS in relation to the commencement of diagnosis was $p<0.003$, which is less than 0.05 and hence statistically significant. All the other tests are also <0.05, indicating that there is a statistically significant difference in time to incident. From the figure below, 62Gy/31 dosage and fractionations had the worst outcome with 100% rate of death in the two-year duration. This is however due to the fact that only the single patient received this form of treatment.

Figure 1: Overall Survival

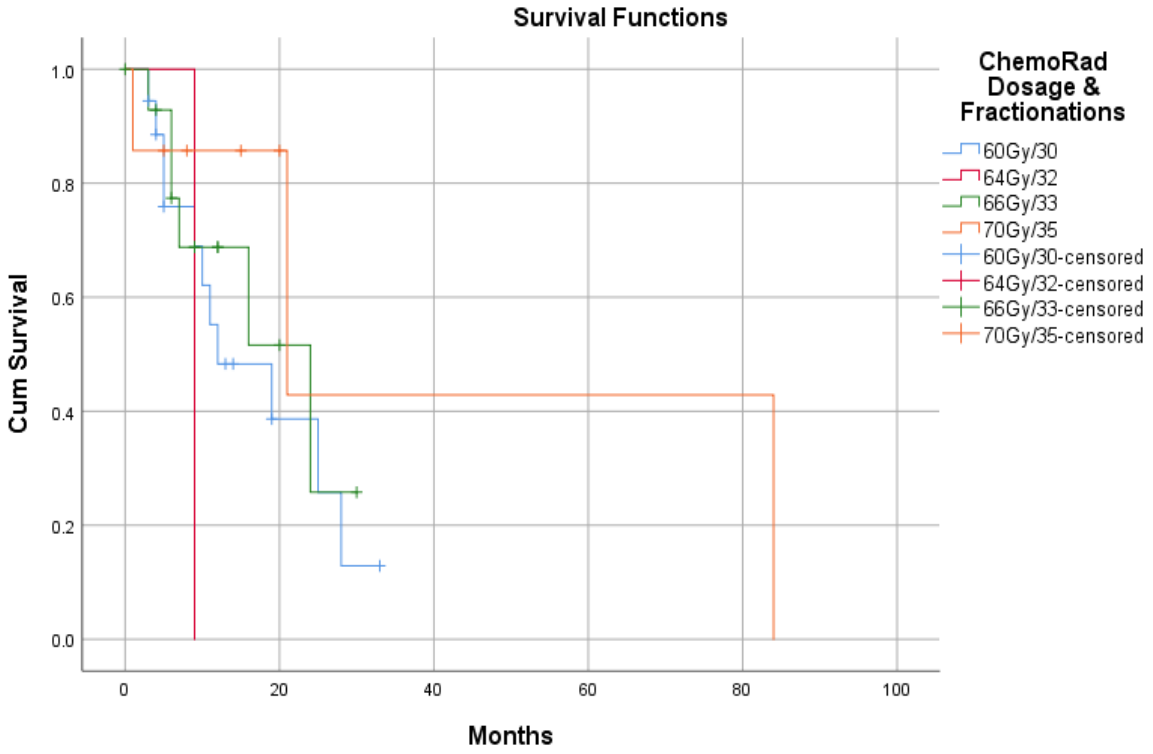


4.4.2 Local- Regional Failure-Free Survival (LRFFS)

During the follow-up period, 24 individuals experienced locoregional recurrences. The overall cohort of patients had a 2-year LRFFS rate of 84 percent. Only 8% of the total patients experienced local recurrences therefore 92% of the patients exhibited local failure-free survival. Regional recurrences were seen in 8% of the total patients therefore 92% of the patients exhibited regional failure-free survival. Age, T category, N category, AJCC stage, and body mass index were found to be insignificant prognostic factors for LRFFS in univariate analysis.

The independent prognostic importance of the following variables was verified by multivariate analysis: Age, AJCC stage, and BMI. The p-Value of the LRFFS in relation to the start of treatment was p=0.310, which is >0.05 and thus statistically insignificant, according to the log-rank. All of the tests are also >0.05, indicating no significant difference in time to event.

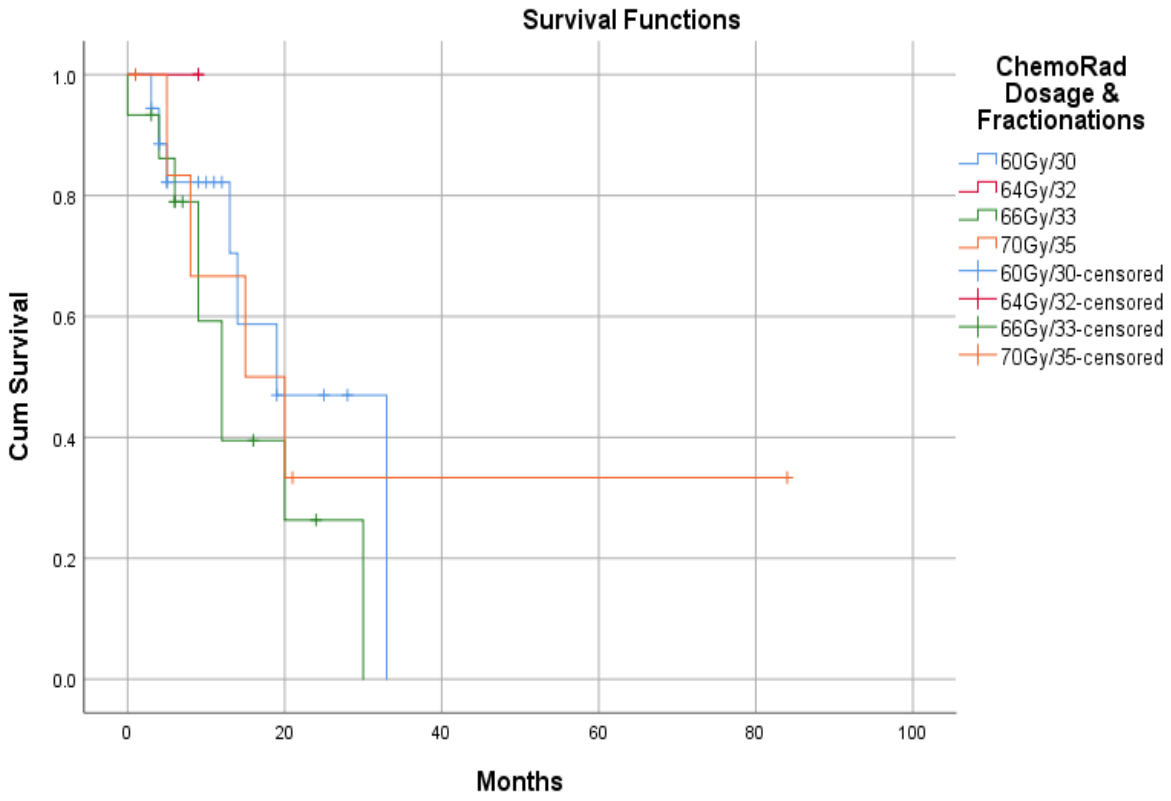
Figure 2: LRFFS



4.4.3 Distant Metastasis-Free Survival (DMFS)

During the follow-up period, 20 individuals had distant metastases. Metastatic recurrence was seen in 14% of the total number of patients. The overall cohort of patients had an 86% 2-year DMFS rate. Age, T category, N category, AJCC stage, and body mass index were found to be insignificant prognostic factors for DMFS in univariate analysis. The independent prognostic importance of these variables was verified by multivariate analysis of age, AJCC stage, and BMI. The log-rank p-Value of the DMFS in relation to treatment initiation was p=0.519, which is greater than 0.05 and hence statistically insignificant. All of the tests are also >0.05, indicating that there is no statistically significant difference in time to incident.

Figure 3: DMFS



Tables 12 and 13 detail the results of the univariate and multivariate analyses.

Table 1: Univariate Analysis

	No.	2-year OS	2-year DMFS	2-year LRFS
Age		P<0.001	P=0.221	P=0.791
18-29	27	52%	67%	33%
30-39	38	66%	57%	43%
40-49	25	60%	50%	50%
50-59	24	50%	27%	73%
60-69	19	21%	40%	60%
70-80	8	25%	N/A	N/A
T category		P=0.101	P=0.227	P=0.949
T0	2	0%	100%	0%
T1	22	41%	43%	57%
T2	31	64%	67%	33%
T3	44	39%	44%	56%
T4	42	47%	42%	58%
N category		P=0.126	P=0.647	P=0.933
N0	16	63%	0%	100%
N1	30	60%	38%	63%
N2	70	36%	52%	48%
N3	25	54%	57%	43%
Stage		P=0.064	P=0.549	P=0.979
II	24	75%	33%	67%
III	67	43%	48%	52%
IVa	50	50%	53%	47%
BMI		P=0.638	P=0.928	P=0.154
≤25	117	50%	43%	57%
≥26	24	54%	71%	29%

BMI, body mass index; OS, overall survival; LRFS, loco regional failure-free survival; DMFS, distant metastasis-free survival.

Table 2: Multivariate Analysis

		P value	HR	95.0% CI	
Overall survival rate:					
Age		<0.001	1.86	1.366	2.532
Stage		0.408	1.318	0.685	2.535
BMI		0.503	0.686	0.228	2.066
Local control rate:					
T category		0.743	1.339	0.234	7.642
Regional control rate:					
N category		0.474	0.025	<0.001	606.264
Distant metastasis-free survival rate:					
BMI		0.759	0.953	0.702	1.295
N category		0.392	2.584	0.294	22.728

HR, hazard ratio; CI, confidence interval; BMI, body mass index

The results of this study show that 30.8% of patients got recurrences. From the time of last Chemoradiotherapy treatment to the time of recurrence, it took a Mean ± SD of 41.35 ± 33.610 weeks for the disease to recur. This means that the overall time of recurrence might be 8 weeks on the lower side and 75 weeks on the higher side with a median of 29 weeks. Forty-six percent of these recurrences were metastatic, and 27% for regional and local recurrence respectively. The Liver was the commonest site of distant metastasis at 38%, followed by skeletal metastasis (27%), lungs (23%) and brain (12%). Patients managed with 2D-EBRT had more local-regional recurrence than those treated with 3DCRT. The rate of distant metastasis between the two radiotherapy modalities was almost similar.