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COMPARATIVE EVALUATION OF QUALITY OF LIFE IN PATIENTS AFTER TREATMENT WITH THREE PALLIATIVE RADIOTHERAPY SCHEDULES IN ADVANCED HEAD AND NECK CANCER.

Oncology/Radiotherapy

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ABSTRACT

Aim & Objectives- To compare the locoregional regression of disease, the incidence of acute toxicity and patient compliance among the 3 hypofractionated radiotherapy regimens.

Material & Methods-

- All patients are given palliative radiotherapy using Varian Linear accelerator using 2D technique in SSG hospital, Vadodara.
- Sample size- 90.
- Patients are randomly divided into 3 groups with each group containing 30 patients.
- One group is given conventional hypofractionated regimen is 30 Gy in 10 fractions, 3 Gy per fraction 5 times a week.
- Second group is given quad shot protocol which delivers 44.4 Gy in 12 fractions, 3.7 Gy per fraction twice a day, with 6 hours interval between 2 fractions for 2 consecutive days and repeated every 3 weekly 3 times.
- The third group is given 36 Gy in 6 fractions, 6 Gy per fraction repeated every weekly for 6 weeks.
- 4 weeks after completion of treatment, patients were assessed for pain relief according to rupee scale.
- Treatment response was assessed using RECIST 1.1 criteria.
- Mucositis and skin reaction is graded according to NCI-CTCAE.

Results-

- Out of the total 90 patients, 69 patients completed the treatment.
- Quad shot protocol was superior to 30 Gy/10# in local response.
- 36 Gy/6# was not inferior to quad shot protocol in local.
- Pain relief was comparable on all three groups without any significant difference.
- The incidence of mucositis and radiation dermatitis was comparable on all three groups without any significant difference.

Conclusion- 36 Gy in 6 # is recommended as the palliative radiotherapy schedule of choice since it has similar local control and pain relief as quad shot protocol with similar toxicity and it is comfortable for most of the patients.

KEYWORDS

Local control, Pain relief, Toxicity.

INTRODUCTION:-

Patients with advanced head and neck cancer usually do not respond well to standard fractionated radiotherapy or chemotherapy or any surgery. With any of these treatments, the disease cannot be cured. Treating such patients with curative intent only makes the patients suffer due to acute toxicity rather than curing the disease. In such patients, our treatment goal is to provide the best palliative care possible. Though the survival of the patient is increased only by few months, the quality of life of the patients and the care givers is significantly improved. Without any such palliative care, patient suffers severe pain, insomnia, foul smell from the wound due to infections or maggot infestations which makes the quality of life of patient in his survival period very poor. So, it is really important to focus on improving the quality of life of these patients rather than curing them.

Standard conventional fractionated radiotherapy delivers 2 Gy per fraction in 35 fractions which delivers a high Biological Effective Dose (BED) to tumour and early reacting normal tissues like skin and mucosa, while delivering a low BED to the late reacting normal tissues like spinal cord. This results in good tumour control along with acute toxicities like mucositis and skin reactions, which can be easily managed [1]. While it is uncommon to see severe late toxicities like myelopathy and paralysis in standard conventional fractionation. It is very important to prevent these late toxicities in a patient treated with curative intention, since we expect the patient to survive for a longer duration [2].

On the other hand, patients treated with palliative intention are usually not expected to have a life span of more than one year. In these patients our aim is to provide optimal tumour control with minimal acute toxicities and lesser hospital visits and to keep the patient comfortable till the time he survives. So, hypofractionated radiotherapy is used which delivers higher dose of radiation per fraction delivering the desired dose in lesser fractions. The time interval between each fraction might be increased, giving the early reacting normal tissues more time to regenerate, thus reducing acute toxicities [5][6]. This delivers optimal BED to the tumour and a tolerable BED to the early reacting normal tissues while delivering a higher BED to the late reacting normal tissues. Since the patient is not expected to have a longer life span to experience these late toxicities, high BED to late reacting tissues can be neglected.

The conventional hypofractionated regimen is 30 Gy in 10 fractions, 3 Gy per fraction 5 times a week. Many studies show quad shot protocol (RTOG 8502) which delivers 44.4 Gy in 12 fractions, 3.7 Gy per fraction twice a day, with 6 hours interval between 2 fractions for 2 consecutive days and repeated every 3 weekly 3 times has optimal tumour control with tolerable acute toxicities when compared to other hypofractionated regimens. In SSG hospital, Vadodara we practice a regimen of 36 Gy in 6 fractions, 6 Gy per fraction repeated every weekly for 6 weeks which is well tolerated by most of the patients with a good tumour control in many patients. This trial compares the tumour control along with the acute toxicities and compliance of the patients who received three above mentioned radiotherapy schedules with respect to quality of life, relief of symptoms and tolerability.

Study Hypothesis: -

Whether the tumour control and tolerance in 36 Gy in 6 fractions regimen is comparable with other standard hypofractionated regimens or not.

Aims And Objectives: -

To compare the locoregional regression of disease, the incidence of acute toxicity and patient compliance among the 3 hypofractionated radiotherapy regimens.

Study Design: -

Study Type: Prospective Interventional study.
Study Site: Department of Radiation Oncology, Medical College

Baroda, Vadodara.
Study duration: July 2023 to July 2024
Sample size: 90

Inclusion Criteria:

- Patients with age between 20 to 70 years.
- Patients with advanced head and neck squamous cell carcinoma who have not received any form of chemotherapy or radiotherapy or surgery previously.
- Patients who received palliative hypofractionated radiotherapy.
- Patients in stage cT4a or T4b, any N and any M according to TNM classification of head and neck cancer.
- Patients for whom curative surgery or definitive Radio chemotherapy is not possible.
- Patients in ECOG 0,1,2.
- Patients who give consent to receive palliative hypofractionated radiotherapy.

Exclusion Criteria:

- Patients with age of less than 20 and more than 70.
- Patients with advanced head and neck cancer who have received any form of chemotherapy or radiotherapy or surgery previously.
- Patients having any histological type other than squamous cell carcinoma
- Patients who received curative standard fractionated radiotherapy.
- Patients in stage cT1, T2, T3 or M1 according to TNM classification of head and neck cancer.
- Patients for whom curative treatment is possible.
- Patients in ECOG 3,4.
- Patients who do not give consent to receive palliative hypofractionated radiotherapy.

MATERIALS AND METHODS: -

- All patients are given palliative radiotherapy using Varian vital beam Linear accelerator using 2D technique in SSG hospital, Vadodara.
- BED is calculated by the formula BED=, where D is the total dose delivered, d is the dose per fraction and α/β ratio is 3 for late reacting normal tissues and 10 for tumour and early reacting normal tissues.
- EQD_2 is calculated by the formula
- Patients are randomly divided into 3 groups.
- One group is given conventional hypofractionated regimen is 30 Gy in 10 fractions, 3 Gy per fraction 5 times a week which has a BED of 39 Gy to tumour and a BED of 60 Gy to late reacting normal tissues. It has a EQD_2 of 32.5 Gy to tumour and EQD_2 of 36 Gy to late reacting normal tissues [4].
- Second group is given quad shot protocol which delivers 44.4 Gy in 12 fractions, 3.7 Gy per fraction twice a day, with 6 hours interval between 2 fractions for 2 consecutive days and repeated every 3 weekly 3 times which has a BED of 60.83 Gy to tumour and a BED of 99.6 Gy to late reacting normal tissues. It has a EQD_2 of 50.69 Gy to tumour and EQD_2 of 59.5 Gy to late reacting normal tissues.
- The third group is given 36 Gy in 6 fractions, 6 Gy per fraction repeated every weekly for 6 weeks which has a BED of 57.6 Gy to tumour and a BED of 108 Gy to late reacting normal tissues. It has a EQD_2 of 48 Gy to tumour and EQD_2 of 64.8 Gy to late reacting normal tissues [3].
- 4 weeks after completion of treatment, patients were assessed for pain relief according to rupee scale.
- Treatment response was assessed using RECIST 1.1 criteria.
- Complete response is complete clinical or radiological disappearance of disease.
- Partial response is clinical or radiological reduction in size of disease by >30%.
- Stable disease is if the change in size of the disease is between 30% reduction to 20% increase.
- Progressive disease is if there is clinical or radiological increase in size of the disease by >20%.
- Mucositis and skin reaction is graded according to NCI-CTCAE.
- Grade 1 mucositis is asymptomatic needing no intervention.
- Grade 2 mucositis is moderately painful ulcer not interfering with oral intake.
- Grade 3 mucositis is severe pain interfering with oral intake. Grade 4 involves severe bleeding, requires emergency intervention and grade 5 is death.
- Grade 1 radiation dermatitis is dry desquamation.
- Grade 2 radiation dermatitis is wet desquamation in areas of skin folds and creases.
- Grade 3 radiation dermatitis is wet desquamation in areas of skin other than folds and creases. It includes bleeding due to minor trauma or abrasions [7].
- Grade 4 in skin necrosis or full thickness dermatitis requiring skin grafting and grade 5 is death.

DATA ANALYSIS AND RESULTS:

Analysis will be done with using M.S Excel and chi-square test.

SAMPLE SIZE- 90.
A- 30 Gy in 10 #
B- 36 Gy in 6 #
C- Quad shot.
Patients completed treatment-69.

Table 1

	MALES	FEMALES
A	19	11
B	21	9
C	12	18

Table 2- Local Response Based On Recist 1.1 Criteria

	COMPLETE RESPONSE(CR)	PARTIAL RESPONSE (PR)	STABLE DISEASE (SD)	PROGRESSIVE DISEASE(PD)
A	1	11	8	4
B	4	15	4	1
C	5	14	1	1

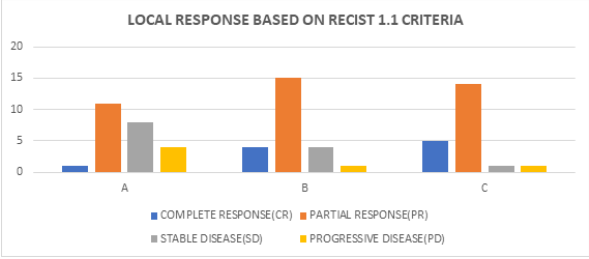


Table 3- Pain Relief Based On Rupee Scale

	<50% Relief	50-75%	>75%
A	9	12	3
B	4	12	8
C	5	9	7

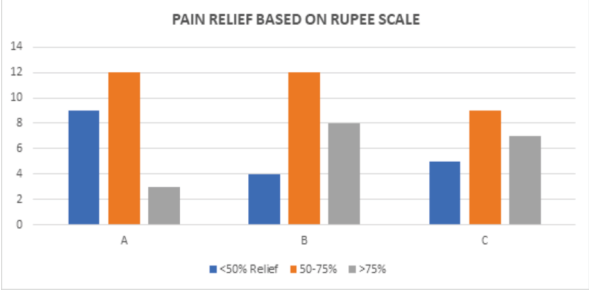


Table 4- Mucositis NCI-CTCAE Grades

	I	II	III	IV	V
A	2	11	8	3	0
B	1	13	7	3	0
C	0	10	7	4	0

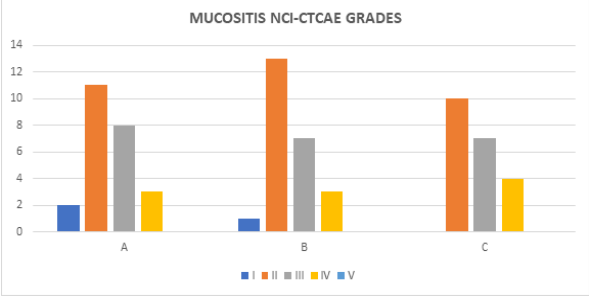
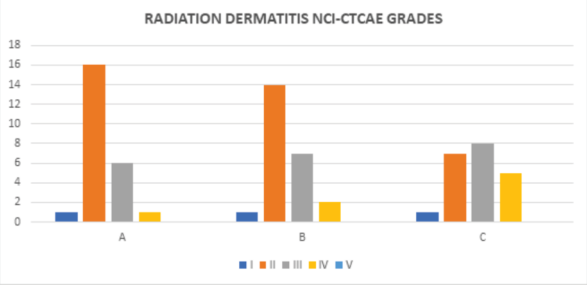


Table 5- Radiation Dermatitis NCI-CTCAE Grades

	I	II	III	IV	V
A	1	16	6	1	0
B	1	14	7	2	0
C	1	7	8	5	0



RESULTS:

- 69 patients out of 90 completed treatments; 21 lost to follow-up [A (6), B (6), C (9)].
- Group B is superior in local response than A(p-value=0.0176).
- Group C is not inferior to B in local control. (p-value=0.625).
- Comparable pain relief, mucositis, and radiation dermatitis incidence in all three groups (p-values=0.307, 0.869, 0.303 respectively).
- Out of 69 patients 60 (86.95%) patients felt C would be comfortable, 7 (10.14%) patients felt B would be comfortable and 2 (2.89%) patients felt A would be comfortable.

CONCLUSION:

36 Gy in 6# recommended as the palliative radiotherapy schedule of choice for similar local control and pain relief as quad shot protocol, with similar toxicity and higher patient comfort.

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