Early Physiotherapy on The Outcome of Post-Operative Patients with Squamous Cell Carcinoma of The Head and Neck – A Non-Randomized Controlled Trial

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Abstract

Purpose – To study the effect of early physiotherapy on the outcome of post-operative patients with squamous cell carcinoma of the head and neck. **Methodology**- This study was a non-randomized controlled trial comprising two groups one receiving an early physiotherapy intervention and the other conventional commencement of physiotherapy among post-operative patients with squamous cell carcinoma of the head and neck. Pain intensity, quality of life, and mouth opening were assessed as outcome measures. **Results** – There was a significant improvement in all the outcomes from a baseline homogeneity in both the groups however the improvement was gained faster in the early intervention group and sustained for a long period which reflected in a significant difference in improvement in the follow-up analysis. **Conclusion** - this study recommends the early administration of physiotherapy to the subjects suffering from squamous cell carcinoma of the head and neck after surgery.

Keywords: squamous cell carcinoma, mouth opening, pain, quality of life, cancer care, early physiotherapy.

1. Introduction

There is a considerable increase in oral cancer particularly in the northern parts of India where tobacco chewing has been a predominant social habit [Hassan Saad R et al 2020]. Despite that, it was regarded as the sixth most common cancer worldwide [Lazaro et al, 2020]. Oral squamous cell carcinoma is about 90% of the histologic type of oral cancer [Srinath et al, 2018] and may or may not be preceded by oral potentially malignant disorders. Squamous cell carcinoma is one of the most common malignant tumors of the oral cavity and it is the leading death-causing carcinoma. Adenoid squamous cell carcinoma (ASCC) prevalence is about 2%-4% of all squamous cell carcinoma (SCC) cases. Initially, it was described by Lever in 1947 as adenoacanthoma of the sweat glands.[Lazaro et al, 2020] The sun-exposed areas of the skin, particularly on the head and neck of elderly men, are more commonly affected.[Hassan Saad R et al 2020] It arises from dysplastic oral squamous epithelium. Therefore, it is more frequently seen among men than women, when they are exposed to a high risk of habits like tobacco chewing or smoking and alcohol consumption. About 95% of all oral carcinoma are malignant. Therefore the annual rate of incidence and mortality rate might varies based on different genders, age groups, and races. Usually, oral squamous cell carcinoma

of the mandibular region will have a lower survival rate than the other carcinoma. It is managed by a combination of surgery, radiotherapy, and chemotherapy, depending on the place, stage, and, TNM classification [Louise Kent M et al, 2008 Johnson J et al, 2015]. Quality of life is a major component that deals with the management of patients with squamous cell carcinoma and it involves a psychological approach. Physical examination such as stench, pain, and oozing may result in severe psychological symptoms, worsening the wounds [Steiner et al, 2015; Pauli et al, 2013]. Squamous cells are specialized cells that are present in the outer layer of human skin and also in the mucous membranes. The mucous membrane is moist tissue that lines human body cavities like airways and intestines. Head and neck squamous cell carcinoma (HNSCC) is a specific type that develops in mucous membranes of the mouth mostly but also in the nose, and throat. This prospective cohort study wanted to find the effect of early physiotherapy management in the rehabilitation of HNSCC. Thus, this study tried to determine the effect of early physiotherapy on the outcome of post-operative patients with squamous cell carcinoma of the head and neck – A non-randomized controlled trial.

2. Methodology

This study was conducted in a single cancer specialty hospital, HCG Cancer Centre, Ahmedabad. The study was performed from 30.09.2019 to 22.03.2020 and from 01.08.2020 to 24.07.2021 (a total duration of 18 months approximately). The study was approved by the Research Advisory Committee and the Institutional ethical committee at Madhav University, Sirohi, Rajasthan, India. The ethical approval letter is attached in the appendix. The sample size for the study was calculated using the Gpower software version. As per the estimation, a total of 38 samples were required which means 19 for each group. Accounting for contingency 10% of the sampwasere increased which resulted in 21 samples in each group. Hence totally 42 samples were selected for the study and were allotted 21 per group. The study adopted a convenient sampling technique in the form of consecutive sampling to select samples from the population. A random

allocation was adopted to distribute the 42 samples into both groups, using a random number table method. The allocation details were kept in an opaque cover which was stapled and secured from opening to conceal the sequence until interventions were assigned. A physiotherapist who was not the part of intervention or outcome analysis was used to generate the random allocation sequence, and he enrolled participants and also assigned participants to interventions. He was a postgraduate with a minimum of 5 years of research experience in handling sampling. A physiotherapist who was not involved in the allocation of intervention delivery was used for outcome analysis. He was a post-graduate with a minimum of 5 years of experience in handling the outcome measures. He was blinded to the intervention and groups to which the subjects belong. All patients diagnosed with oral squamous cell carcinoma that underwent surgical intervention in HCG Cancer Centre, Ahmedabad with or without radiotherapy will be included in this study. The inclusion criteria were, patients who were clinically diagnosed with cancer cavioris or cancer oropharynges who were treated surgically, age Age > 18 years of all sex, and who gave Informed consent were only selected.

Patients were excluded if they presented with bone reconstruction surgery or grafting, motor nerve damage occurred while surgery, affecting the functionality of the neck or shoulder. known severe uncontrolled systemic diseases and musculoskeletal disease with symptoms that may influence the study variables externally, rheumatoid arthritis, fibromyalgia, temporomandibular arthritis, neurological disease other industrial injuries, psychiatric disorders, dementia, and other conditions that may influence the participation, who are unable to cooperate. The intervention provided is displayed in figure 1.

The maximal mouth opening of each patient will be measured before, after 15 sessions of therapy, and at the time of one month review following physiotherapy. The mouth opening was quantified through a standardized protocol provided by Dijkstra et al in 1995. The subjects were instructed to open their mouth to the maximum possible extent so that no further opening was achievable. The distance between the incisal edge of the upper jaw incisor tooth to the incisal edge of the lower jaw incisor

tooth was assessed using a calibrated fiber scale (ruler) these values were recorded in millimeters. An average was taken between the three readings taken for each individual. To limit the inter-examiner all the assessment was performed by only one examiner. Pain during jaw motions will be measured using a visual analog scale. The patients were asked to rate the pain on a scale of 10. In this lower, the values meant less pain more values meant severe pain. For E.g. patients who selected 0 had no pain whereas patients who selected 4 or 5 had moderate pain compared to those who selected 8 or 9 with severe pain. The pain was reported during mouth opening only and not at rest. Quality of life will be assessed using a QOL-Questionnaire-for-cancer-patients which is a scale with a total score of 110.

Statistical tests

The results of the study were analyzed by a professional statistician using SPSS version 26. The following statistical analysis will be used in the study. The data of the study are both parametric as well as non-parametric. The mouth opening was a parametric data hence independent t-test was used for the between-group analysis of the pre-test, post-test, and the follow-up values. For the within-group analysis, Related-Samples Friedman's Two-Way Analysis of Variance by Ranks was used and the Bonferroni test was used for pairwise comparison or the post hoc analysis.

The VAS and QOL were non-parametric data, hence Mann-Whitney U test was used for the between-group analysis of the pre-test, post-test, and follow-up values. For the within-group analysis, Repeated measures Analysis of Variance (ANOVA) was used and the Bonferroni test was used for pairwise comparison or the post hoc analysis.

3. Results

Totally 42 subjects accounted for the study results as there were no dropouts. The between-group analyses of pre-test values of the VAS scale show that the mean ranks of Group A and B were 21.86 and 21.14 respectively. The Mann-Whitney U test performed to find the difference between them showed there was no significant difference with a Z value of -0.200 and a p-value of 0.841. The between-group analyses of post-test values of the VAS scale show that the mean ranks of Group A and B were 27.24 and

15.76 respectively. The Mann Whitney U test performed to find the difference between them showed there was a significant difference with a Z value of -3.145 and p-value of 0.002. The between-group analyses of follow-up scores of the VAS scale show that the mean ranks of Group A and B were 31.57 and 11.43 respectively. The Mann Whitney U test performed to find the difference between them showed there was a significant difference with a Z value of -5.455 and p-value < 0.001.

The between-group analyses of pre-test values of the QOL scale show that the mean ranks of Group A and B were 20.74 and 22.26 respectively. The Mann-Whitney U test performed to find the difference between them showed there was no significant difference with a Z value of -0.408 and p-value of 0.683. The between-group analyses of post-test values of QOL show that the mean ranks of Group A and B were 12.12 and 30.88 respectively. The Mann Whitney U test performed to find the difference between them showed there was a significant difference with a Z value of -4.993 and p-value < 0.001. The between-group analyses of follow-up scores of QOL show that the mean ranks of Group A and B were 11.00 and 32.00 respectively. The Mann Whitney U test performed to find the difference between them showed there was a significant difference with a Z value of -5.557 and p-value < 0.001.

The within-group analysis of the three values namely pre-test, post-test, and follow-up scores of group A for VAS scores using Friedman's Two-Way Analysis of Variance by Ranks shows that there was a significant difference between the three values with a p-value < 0.001. The Post Hoc pairwise analysis using Bonferroni correction shows that there was a significant difference between pre-test values and the other two values (p< 0.001) but there was no significant difference between post-test and the follow-up values. (0.0.064). The within-group analysis of the three values namely pre-test, post-test, and follow-up scores of group B for VAS scores using Friedman's Two-Way Analysis of Variance by Ranks shows that there was a significant difference between the three values with a p-value < 0.001. The Post Hoc pairwise analysis using Bonferroni correction shows that there was a significant difference between all three

pairs compared with a value of p< 0.001. The analysis is shown in table 5.8. and figure 5.2.

The within-group analysis of the three values namely pre-test, post-test, and follow-up scores of group A for QOL scores using Friedman's Two-Way Analysis of Variance by Ranks shows that there was a significant difference between the three values with a p-value < 0.001. The Post Hoc pairwise analysis using Bonferroni correction shows that there was a significant difference between all three pairs compared with a value of p< 0.001.

The within-group analysis of the three values namely pre-test, post-test, and follow-up scores of group B for QOL scores using Friedman's Two-Way Analysis of Variance by Ranks shows that there was a significant difference between the three values with a p-value < 0.001. The Post Hoc pairwise analysis using Bonferroni correction shows that there was a significant difference between all three pairs compared with a value of p< 0.001.

Figure 1 – Early physiotherapy Intervention used for the study

Phase	Timing	Diet Therapy
Phase 1	Within 24 hours after surgery to 7days after surgery	Non-chewing diet - Cold therapy over joint 1×20 minutes, (minimally) 5 times per day Condylar rotational exercises (passive opening and closing, 20 repetitions, 3 times per day; active opening and closing, 20 repetitions,3 times per day) Grade I joint distraction Grade II joint distraction toward end of phase 1 Oral re-education with avoidance of Para functions
Phase 2	From 1 to 3 weeks after surgery	Moist heat application over muscles 20 minutes before exercises, cold application over joint after exercises Coordination exercise using a mirror 1. Condylar rotational exercises as in phase 1 2. Active mouth opening and closing 3. "Mandibular snake": protrusion, depression, retrusion, elevation, return to neutral position Range of motion exercises (until pain limit, not over pain limit) 1. Insertion of tongue spatula or Thera Bite system 7x7 seconds, 7 times per day 2. Active assisted opening: 10 repetitions, keeping the maximal mouth opening for 30 seconds, 3 times per day 3. Active lateral movement: 10 repetitions keeping the maximum lateral deviation for 30 seconds, 3 times per day 4. Active protrusive and retrusive movement: 10 repetitions, keeping the pro/retrusive deviation for 30 seconds, 3 times per day. Grade II joint distraction - Use of chewing gum
Phase 3	From 4 weeks on after surgery	Transition to solid diet Stabilization exercises 1. Lower jaw maintained in a neutral, slightly open position (lateral manual pressure: 1x6 repetitions, 5 times per day; upward manual pressure: 6 repetitions, 5 times per day) 2. Lower jaw maintained in a closed position (attempting to open the during upward manual pressure: 6 repetitions, 5 times/day) Range of motion exercises 1. Maximum opening (insertion of tongue spatula or TheraBite system: 5x30 seconds, 5 times per day; active assisted, opening: 5 repetitions, keeping the maximum mouth opening for 30 seconds - 1 minute, 3 times per day; active, opening: 5 repetitions, keeping the maximum mouth opening for 30 seconds -1 minute, 3 times per day) 2. Lateral deviation: 10 repetitions, 3 times per day per side Grade III & IV joint distraction, Massage of masticatory muscles, Use of chewing gum.

4. Discussion

The current study was designed to find the effect of early physiotherapy which is defined as physiotherapy from the 2nd Post-Operative Day (POD). Cancer is a universal medical concern and it is a difficult medical problem because the host is majorly asymptomatic yet the condition is widely spreading. This is an untouched part of physiotherapy research compared he other conditions like musculoskeletal and neurological conditions. The patients are so sensitive and fear-filled hence have to be treated with a bio-psycho-social model. In India Cancer is a major health problem, with more or less one million subjects obtaining every year. In India, overall 200,000 patients with head and neck cancer (HNC) have been dealt with every year the counts are very low even in a country like America with just 30,000 occurrences a year.

When observing the mortality rate Cancer accounts for 8 percent of the whole deaths in India. However, the Incidence of HNC primary has displayed to increase with age. Hence, the functional and cosmetic deficiencies are most apparent in HNCs, this category of cancers raptor only 5 percent of all malignancies stage. Worldwide, HNC is captured into evaluated to be the fifth most general cancer with the 7th increased cancer mortality. The most common listed etiologies of HNCs are tobacco and alcohol consumption.

It is also told that the consumption of alcohol in joint with smoking is many of the major not unusual causative components of HNCs. Other causes of HNC-stimulating betel chewing, drinking of hot tea, smoking, alcohol consumption, and human papillomaviruses. Yeole has done an attempt to research the trends in the age-adjusted occurrence rates for the location of HNCs in Mumbai, Bangalore, Chennai, Delhi, Bhopal, and Barshi registries. He identified the correct trend of cancer of the tongue, oropharynx, and larynx where such as bidi smoking is the major risk factor could be demonstrated based on the present database. Oncologists and scientists have made indicative improvements in cancer management in the past decade.

As both the quantity of major cancers patients and the period in their survival are improving, lengthy-time period fitness issues accompanied with major cancers and their solutions are getting more complicated. To get such particular results many sufferers obtain a competitive remedy, including surgical process, chemotherapy, and also radiation therapy. The issues that attain in relevant to the cancer conditions and their treatment differ with the type of cancer, stage of the disease, and type of medical management. Complications may increase in the period between investigations and primary treatment, while primary management, and also while the follow-up.

5. Conclusion

This study was conducted to determine the effect of early physiotherapy on the outcome of post-operative patients with squamous cell carcinoma of the head and neck, using a non-randomized controlled trial. The main objectives of the study were to find the effect of early physiotherapy in improving mouth opening, shoulder function, pain, quality of life, and satisfaction among post-operative patients with squamous cell carcinoma of the head and neck, to find the effect of conventional physiotherapy in improving mouth opening, shoulder function, pain, quality of life and satisfaction among post-operative patients with squamous cell carcinoma of head and neck and finally to find the differences in the prognosis of subjects who received early physiotherapy and conventional physiotherapy among post-operative patients with squamous cell carcinoma of head and neck. There was a significant improvement in mouth opening, pain, and quality of life among the subjects treated with early physiotherapy. Hence this study recommends the early administration of physiotherapy to the subjects suffering from squamous cell carcinoma of the head and neck after surgery.

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