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Protocol For A Longitudinal Prospective Study Investigating Neck Pain, Functional Outcomes, Psychological Distress, And Quality Of Life In Head And Neck Cancer Patients Undergoing Cancer Treatment

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Abstract: Neck pain and disability are prevalent in HNC patients, which can be attributed to the diagnosis itself or its treatment. Neck pain and associated disability may cause psychological distress and subsequently decrease the patients' QoL. This longitudinal prospective study has been undertaken to assess neck pain and related functional and psychological concerns and determine the QOL among HNC patients receiving anti-cancer treatment. 35 head and neck cancer patients undergoing cancer treatment will be enrolled in the study. They will undergo a baseline evaluation before the initiation of treatment and will be followed up at 1st month, 2nd month, and 3rd month.

Key words – Anxiety, depression, head and neck cancer, neck disability, neck pain, QOL

INTRODUCTION

Yearly, India exhibits around 0.2 million cases of head and neck cancer (HNC). According to reports, the risk of developing HNC increases with age. Globally, it is recognised as the fifth most common cancer, with the seventh highest illness fatality rate (1). HNC can be treated with surgery, radiation therapy (RT), chemotherapy (CT), or a combination of these treatments (2). Previous studies have shown that individuals receiving surgical treatments using flap repair frequently experience substantial long-term musculoskeletal issues. Adverse consequences of surgical treatment include difficulty swallowing, neck and shoulder discomfort, sleep disruptions, weariness, and increased anxiety (3).

Pain is the most prevalent and disabling symptom in HNC, affecting around 70% of people. The symptoms of HNC-related pain can vary greatly and frequently mirror other main pain syndromes (4). Pain can be caused by tumour invasion, surgical procedures, or treatment-related problems such as dysphagia or neuropathy, which occur in up to 80% of individuals undergoing RT, CT, or a combination of both (5). Pain can be nociceptive, neuropathic, or myofascial, and it is frequently accompanied with functional impairment in the shoulder and neck due to surgical resections or fibrotic alterations (6).

Pain, regardless of origin, causes significant psychological discomfort and influences patients' daily activities and overall quality of life (QOL). It may also affect daily activities and general well-being (7). This longitudinal study is designed to explore the progression of neck pain and associated problems over time,

aiming to incorporate preventive and therapeutic measures into standard care protocols, thereby improving rehabilitation outcomes for HNC patients.

STUDY AIMS AND OBJECTIVES

Aim: To evaluate the progression of neck pain and associated concerns in patients with HNC receiving anti-cancer treatment.

Objectives: To assess neck pain and related functional and psychological concerns and determine the QOL among HNC patients receiving anti-cancer treatment.

RESEARCH METHODOLOGY

Study design: This will be a prospective longitudinal cohort study evaluating the neck pain, functional impairments, psychological issues, and QOL in HNC patients receiving anti-cancer treatment.

Population and sample: Patients will be enrolled from a tertiary cancer hospital at Belagavi, Karnataka. The inclusion criteria are adults (over 18 years) diagnosed with HNC, regardless of gender, above 18 years of age, and undergoing surgery, radiation therapy, or chemotherapy, or concomitant therapies. The patients will not be included if they are not willing to participate, have metastasis, are diagnosed with other cancers, or have Cognitive impairment or psychiatric disorders.

Sampling strategy: Non-probability convenience sampling method will be used for the recruitment of the participants. The sample size is 35., The calculation is done using the technique of estimating sample size for the Paired "t" test.

Participant selection and recruitment: Patients will be asked to fill out a written informed consent form confirming their participation in the study. Screening will ensure adherence inclusion and exclusion criteria. Patients meeting the eligibility criteria will undergo baseline evaluation using PAIN-DETECT, FACT-H&N, Neck Disability Index, and HADS 2 to 3 days before treatment initiation. Then, the regular follow-up assessments will be conducted at predefined intervals at the end of the 1st month, 2nd month, and 3rd month.

Data collection: Baseline data collection will include demographics, cancer diagnosis, stage/grade, planned treatment, and previous treatment. To assess the neck pain severity and categorise the pain, PDQ will be used. It has 9 questions related to the severity, temporal, and spatial characteristics of pain. The final score is from 0 to 38, which categorizes the pain as nociceptive (0-12), uncertain (13-18), or certainly neuropathic (19-38) (8). To asses the neck impairments, NDI will be used which categorises the disability as none or minimal (0-4), mild to moderate (5-24), and complete (25-50) (9). HADS will be used to assess the psychological status (anxiety and depression) of the patients, with the scores indicating non-cases, borderline cases, and clear cases (10). FACT-H&N will be used to assess the QOL of the patients. It has four subscales measuring QOL across physical, social, emotional, and functional domains (11).
Baseline evaluations will be conducted face-to-face, while follow-up data may be collected either in person or via telephone to enhance retention.

Statistical analysis: Descriptive statistics will summarise participants' characteristics and outcomes. the data. Repeated measurements of neck pain-associated variables will be compared using **a** paired "t" test. Categorical variables will be analysed using the Chi-square, Likelihood ratio or Fisher's exact test will be used. A p-value < 0.05 will denote statistical significance. SPSS software version 29.0.10 will be used for analysis.

Ethical considerations: This study is approved by the Research and Ethical Committee, KLEU Institute of Physiotherapy, Belagavi. The study emphasises voluntary participation, and participants can drop out of the

study at any point in time without any penalty. The study observes that no risk is involved in the participation. The information provided by the participants will be confidential and safely secured.

IV. RESULTS AND DISCUSSION

Neck pain is a significant concern among individuals diagnosed with HNC, often resulting from the disease itself or its treatment modalities (7). Neck pain and functional impairments increase the risk of emotional distress among these patients and significantly affect their quality of life. Understanding the temporal course of neck discomfort, functional limitations, and psychological distress is critical for initiating early interventions. Despite advances in cancer therapy, rehabilitating HNC patients remains a challenging problem, frequently demanding specialised therapies to suit their particular requirements (1).

By combining physical (pain, disability), emotional (anxiety, depression), and QoL criteria, the study has the potential to give a comprehensive understanding of the impact of cancer and its treatment on patients. The study will provide doctors with practical insights by identifying important periods of increasing symptom load (e.g., one month after treatment), promoting early intervention with physiotherapy and psychological support, and emphasising the importance of routine monitoring using validated instruments. The study will focus on the dynamic pattern of neck pain and impairment in HNC patients during therapy. The study will also monitor changes in psychological state and QOL during the investigation.

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