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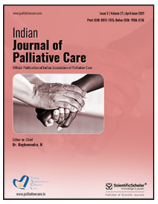

Original Article

Optimising Initial Pain Management and its Influence on Compliance and Treatment Abandonment in Newly Diagnosed Head-and-Neck Cancer Patients: A Real-world Experience

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ABSTRACT

Objectives: Improper pain management is a significant contributing factor and a potential correctable factor for low cure rates of head-and-neck cancer (HNC) patients. This study aims to assess the significance of the Quantitative Improvement Programme (QIP) in evaluating pain levels and its correlation with treatment compliance in recently diagnosed HNC patients undergoing curative treatment at a surgical oncology outpatient department (OPD). The study was conducted from January 2022 to August 2023 at a tertiary cancer care centre in Northeast India.

Materials and Methods: This cohort study used secondary data. We implemented the QIP in December 2022. There were 204 patients in the non-implemented group (NIG) (January 2022 to December 2022), and 110 patients were in the implemented group (IG) (January 2023 to August 2023).

Results: The study included 314 HNC patients. The mean age was 57 years, and the male-to-female ratio was 3:1. More than two-thirds (70%) of patients presented with pain. Pain assessment was carried out in 63% (120) of patients in the NIG and 86% (95) patients in the IG and was found to differ significantly ($P < 0.0001$) between the groups. Treatment abandonment (default before starting treatment) was reported amongst 23% in the NIG, compared to 16% in the IG. 41% (85) of patients in the NIG and 39% (43) in the IG reported non-compliance with treatment (breaks after commencing treatment). There were only 7% of patients from the NIG and 4% of patients from the IG who experienced unfavourable events (relapse, death and treatment failure). Of the various factors analysed, we found age as the single most significant predictor of compliance to treatment (age 18–39 years: Risk ratio [RR] = 2.482, 95% confidence interval [CI]: 0.88, 6.99 [$P < 0.08$]; age group 40–64 years: RR = 0.54, 95% CI: 0.33, 0.90 [$P < 0.01$]).

Conclusion: QIP for pain management resulted in efficient pain assessment, enhanced patient compliance and reduced rates of treatment abandonment. The study findings mandate QIP for effective pain management of HNC patients in all cancer centres.

Keywords: Early pain assessment, Treatment compliance, Head-and-neck cancer, Quality improvement programme, Structured operational research and training initiative, Treatment abandonment

INTRODUCTION

Head-and-neck cancer (HNC) ranks seventh in terms of global cancer prevalence, with around 57.5% and 30% in Asia and India, respectively, with a greater occurrence in the northeastern region of the country. The major concern is increased incidence on the one hand and the lower cure rates in comparison to the developed nations. The advanced stage at diagnosis, poor compliance to treatment and lack of healthcare facilities are the important contributors to low cure rates. Improper pain management is considered a significant contributing reason to poor compliance. Effective pain management can enhance both quality of life and treatment compliance.[1,2]

Pain is one of the most common symptoms in HNC patients. A recent review of the literature revealed that 64% of patients with cancer report pain as a chief complaint,

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59% of the patients receiving anticancer treatment report pain and 33% of the patients complain the same even after completion of curative treatment.[3] Unawareness or difficulty in recognising pain as a problem leads to significant distress, treatment-related breaks and non-compliance towards cancer treatment.[4,5] It is vital to assess and manage pain in the initial visit and also follow it through the entire treatment course to improve overall quality of life and cancer treatment.[5,6] To summarise, cancer-related pain is to be treated as effectively as cancer itself.[6]

This study aims to evaluate the role of the Quantitative Improvement Programme (QIP) for pain assessment and its association with treatment compliance in newly diagnosed HNC patients treated with curative intent presenting to the surgical oncology outpatient department (OPD) from January 2022 to August 2023 at the tertiary cancer care centre in Northeast India.

MATERIALS AND METHODS

Study design

This was a cohort study involving a record review of secondary programme data.

General setting

Cachar Cancer Hospital and Research Centre (CCHRC) was initially established in 1992 by Cachar Cancer Hospital Society as a not-for-profit non-governmental Organisation (NGO) in Silchar. 80% of the population visiting the hospital are daily wagers facing financial and transport difficulties; HNC patients constitute around 40% of total patients presenting to surgical oncology OPD. Furthermore, around 85% of these patients are beneficiaries of various government schemes including Ayushman Bharat and Pradhan Mantri Jan Arogya Yojana schemes and funds from NGOs.

Pain management at CCHRC

Most of the HNC patients presenting to CCHRC with a chief complaint of pain are treated with non-steroidal anti-inflammatory drugs and opioids, depending upon the severity. In December 2022, a quality control programme which included training all healthcare workers on pain management and mandatory documentation of pain scores as the fifth vital sign was implemented. This is a National Cancer Grid (NCG) healthcare quality improvement programme developed to improve the awareness of quality pain assessment and management amongst healthcare workers working in the OPD, thereby causing changes in patient compliance.[7] The NCG QI Hub aims to initiate, inculcate and integrate the culture of quality through its immersion educational initiative EQuIP-India - the educational program provides the participants with conceptual understanding and an immersion experience necessary to respond to quality-related problems across a complex environment such as clinical practice settings. We implemented the QIP in December 2022 and categorised the study population as non-implemented group (NIG) (January 2022–December 2022) and implemented group (IG) (January 2023–August 2023) in which we have done a root cause analysis and pareto frequency charting to identify the most common cause and established key drivers and necessary interventions, one of the main key drivers is to compulsory pain assessment and which we added as fifth vital sign in OPD setting, which was recorded before routine clinical examination and later as a part of sustainable intervention, we added digital documentation of pain score in hospital management software (HMS). The pain assessment was scored from 0 to 10 using a numerical rating scale.

Study population

The study population included newly diagnosed HNC patients with curative intent, presenting to surgical oncology OPD between January 2022 and August 2023.

Inclusion criteria

All patients aged more than 18 years with histologically confirmed diagnoses of squamous cell carcinoma of the head and neck were planned for curative treatment in the study period between January 1, 2022, and August 31, 2023.

Data variables, sources of data and data collection

A list of all new HNC patients with curative intent was extracted from HMS, and missing data were retrieved from patient case records. Both were extracted into electronic data using online EpiCollect5 software. Variables included sociodemographic variables (unique ID, age, sex, type of tobacco: Smoking/smokeless/both, alcohol history), clinical variables (performance status, pain assessment, stage and site of cancer) and treatment-related variables (date of diagnosis, plan of treatment, date of initiation of treatment, date of end of definitive treatment, end of treatment response date of last follow up, status at last follow-up and date of relapse).

Operational definitions

Non-compliance (Defaulter)

Patients missing the scheduled treatment appointment and not responding to telephone calls for more than 2 weeks were considered non-compliant. A patient who was receiving treatment elsewhere was not considered as non-compliant or a defaulter.

Unfavourable event

Any relapse, death or treatment failure (not achieving complete remission at the end of definitive treatment) was considered as an event.

Treatment abandonment

Any patient diagnosed as HNC but did not return for the initiation of treatment was considered treatment abandonment.

Statistical analysis

Descriptive analysis was performed by means of proportions for sociodemographic variables (age, sex, tobacco and alcohol use) and clinical factors (comorbidities, those assessed for pain, treatment initiated, etc.) wherever appropriate. Statistical differences between means of quantitative variables with respect to sociodemographic factors, pain scores and cancer stage were calculated using the Mann–Whitney test (non-normal distribution). The Chi-square test was used to study the association between categorical variables. The associations between the compliance and clinico-socio-demographic risk factors were expressed as risk ratio (RR) (adjusted with 95% confidence intervals [CI]) using logistic regression in the Statistical Package for the Social Sciences version 17.0. $P<0.05$ was considered statistically significant.

Ethics approval was obtained from the Institution Review Board, CCHRC, Silchar, India (ECR/925/Inst/AS/2017/RR-21, dated 13 April 2024. As the study involved a review of patient records (secondary programme data), a waiver for written informed consent was obtained.

RESULTS

Sociodemographic characteristics

A total of 314 HNC patient records were analysed. Two hundred four patients were in the NIG (January 2022–December 2022), and 110 patients were in the IG (January 2023–August 2023). The mean age of patients in our study was 57 years. The male-to-female ratio was 3:1. In this study, all the patients used some form of tobacco, of which 55% were smokeless tobacco users, 6% were smokers, and 39% of patients used both. The majority of patients reported alcohol use (80–87%), and one-third (33%) of the patients were found to be underweight [Table 1].

Clinical characteristics

Table 2 summarises the various clinical characteristics in the entire study group and subgroups based on the quality control implementation program. In our study, patients with oral cavity cancer constituted 39%, followed by oropharynx and hypopharynx cancer, both constituting 25% each. Most of the patients (39%) presented with stage III, followed by stage II in 28% and Stage IVa in 17% of the patients. Only 15% of the patients were found to be non-compliant with the treatment. Hypopharynx cancer was more common in the NIG (26%) than in the IG (21%), whereas oropharynx cancer was less common in the NIG when compared to IG (21% and 31%, respectively).

Non-compliance to treatment was found in 41% (85) of patients in NIG and 39% (43) in the IG. Of the 204 patients in the QIP NIG, treatment abandonment was seen in 46 patients (23%), whereas in IG (110 patients), treatment abandonment was seen in only 18 patients (16%). Pain assessment was carried out in 63% (120) of patients in NIG and 86% (95) patients in the IG and was found to differ significantly ($P < 0.0001$) between the groups. Complete

Table 1: Sociodemographic characteristics of newly diagnosed head-and-neck cancer patients assessed for the quality improvement programme of pain assessment and management between implemented and non-implemented groups in a tertiary cancer centre.

Characteristics	Quality Control Programme				Total (*n*=314)	
	Non-Implemented		Implemented			
	n	%	*n*	%	*n*	%
Age						
18–39 years	10	4.9	10	9.1	20	6.4
40–64 years	126	61.8	71	64.5	197	62.7
Above 64 years	68	33.3	29	26.4	97	30.9
Sex						
Male	155	76.0	84	76.4	239	76.1
Female	49	24.0	26	23.6	75	23.9
Tobacco habit						
Smoking	4	2.0	15	13.6	19	6.1
Smokeless	115	56.4	56	50.9	171	54.5
Both	85	41.7	39	35.5	124	39.5
Non-user	0	0	0	0	0	0
Alcohol use						
No	27	13.2	21	19.1	48	15.3
Yes	177	86.8	89	80.9	266	84.7
Body mass index						
Underweight (<18.5)	72	35.3	31	28.2	103	32.8
Normal (18.5–24.9)	108	52.9	73	66.4	181	57.6
Overweight (25–29.9)	19	9.3	6	5.5	25	8.0
Obese (>30)	5	2.5	0	0.0	5	1.6

Table 2: Clinical characteristics of newly diagnosed head-and-neck cancer patients assessed for the quality improvement programme of pain assessment and management between implemented and non-implemented groups in a tertiary cancer centre.

Characteristics	Quality Control Programme				Total (*n*=314)	
	Non-Implemented		Implemented			
	n	%	*n*	%	*n*	%
Tumour site						
Oral Cavity	86	42.2	37	33.6	123	39.2
Oropharynx	43	21.1	35	31.8	78	24.8
Larynx	18	8.8	10	9.1	28	8.9
Hypopharynx	54	26.5	24	21.8	78	24.8
Nasopharynx	3	1.5	4	3.6	7	2.2
TNM staging						
Stage I	15	7.4	1	0.9	16	5.1
Stage II	56	27.5	32	29.1	88	28.0
Stage III	77	37.7	46	41.8	123	39.2
Stage IVa	37	18.1	17	15.5	54	17.2
Stage IVb	15	7.4	10	9.1	25	8.0
Not recorded	4	2.0	4	3.6	8	2.5
Histopathology grade						
Well differentiated	112	54.9	67	60.9	179	57.0
Moderated differentiated	82	40.2	32	29.1	114	36.3
Poorly differentiated	10	4.9	11	10.0	21	6.7
Performance status						
0	7	3.4	3	2.7	10	3.2
1	171	83.8	100	90.9	271	86.3
2	19	9.3	7	6.4	26	8.3
3	3	1.5	0	0.0	3	1.0
4	4	2.0	0	0.0	4	1.3
Pain management						
No	79	38.7	11	10.0	90	28.7
Yes	125	61.3	99	90.0	224	71.3
Plan treatment						
Unimodality	155	76.0	69	62.7	224	71.3
Bimodality	41	20.1	33	30.0	74	23.6
Tri modality	8	3.9	8	7.3	16	5.1
Comorbidity						
No Comorbidity	154	75.5	98	89.9	252	80.5
Single Comorbid	47	23.0	9	8.3	56	17.9
Multiple comorbidity	3	1.5	2	1.8	5	1.6
Compliance to treatment						
Compliant	175	85.80	93	84.50	268	85.40
Non-compliant	29	14.20	17	15.50	46	14.60

TNM: Tumour, Node, Metastasis

response at the end of treatment was similar (91%) in both groups. Unfavourable events (relapse, death and treatment failure) were seen in 14 (7%) patients of NIG and 5 patients (4%) of the IG.

DISCUSSION

This study is the largest single-centre study from India to document the role of QIP in the management of newly diagnosed HNC. In our study, more than two-thirds of patients presented with pain as an initial symptom and the implementation of QIP significantly increased the proportion of pain assessment along with pain management, decreased non-compliance by 3% and treatment abandonment by 6%.

QIP in oncology has shown their impact on treatment outcomes. Kamal and Krzyzanowska[8] discussed the necessity of sharing real-world experiences as delivering cancer faces complex situations. This study was done initially as part of NCG-EQuiP[7] as pain is one of the most common factors in patients presenting with HNC often neglected. Ghei and Khot discussed about 80% of HNC patients present with pain.[6]

In our study, nearly 70% of our patients reported pain, which is correlated with van den Beuken-van Everdingen

et al.[6] study where the prevalence of pain in cancer patients ranged from 52% to 77%; in HNC patients, it was mentioned to be significantly higher and one of the primary symptoms experienced by patients. The reason might be due to the advanced nature of the disease at the time of initial presentation. 7 out of 10 patients had stage 3 or stage 4 at the time of treatment initiation. Pain was assessed and managed in 86% and 62% of IG and NIG, respectively, leading to effective management.

The mean age of the study group was around 57 years. Our findings are consistent with other studies reported from India. In our study, all the patients were tobacco users, of which 90% were using some form of smokeless tobacco. A higher prevalence of tobacco use amongst HNC in comparison with Western studies is reported in various Indian studies. A study from Northeast India by Bhattacharjee *et al*. reported similar findings of high usage of tobacco, particularly the smokeless form.[9] In our study, 87% of the population had a history of alcohol consumption. Oswal *et al*.[12] conducted a district-level household survey to determine the prevalence and determinants of alcohol consumption in the North East Region (NER), which showed a higher prevalence of consumption of alcohol in males; homemade alcohol drinks are very popular in Assamese culture and tribal populations. Data from the National Family Health Survey-4 2015–2016 showed a higher use of the NER, 71%, compared with 50 % in the rest of India.[12] In our study, 4 out of 10 had oral cancer subsite, which is similar to the findings of Chauhan *et al*. and contrary to the findings of Bhattacharjee *et al*. and Kulkarni.[9-11]

In our study, QIP led to significant improvement in pain assessment and management and a decrease in treatment abandonment. Although the compliance rate was better in IG, it was not statistically significant. The reason might be due to the small sample size, short follow-up period and missing data. Ours is the first study to report the effectiveness of the QIP for pain assessment and management. Most of our literature review cites the following barriers as the reasons for ineffective management such as poor pain assessment, lack of knowledge, reluctance to prescribe opioids, unavailability of drugs and lack of sensitisation amongst health workers.[4,13] Implementation of QIP has helped us to overcome these barriers. The study findings necessitate QIP for effective pain management and mandate pain score as the fifth vital sign during the management of HNC patients in all cancer centres.

Limitations

The key limitations are the missing data in case records, the absence of serial pain scores and the quality of life assessment.

CONCLUSION

In our study, QIP resulted in efficient pain assessment and management, enhanced patient compliance and reduced rates of treatment abandonment. Delivering quality cancer care is difficult in complex situations. QIP helps in many aspects of health care, particularly cancer in resource-limited settings, thereby reducing treatment abandonment and improving patient compliance.

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Author's contributions

BVSSKT: Principal Investigator and corresponding author, conception/design of the protocol, acquisition of data, data analysis/interpretation, drafting/critically reviewing the paper, giving approval for the final version to be published. BVSSKT, RK, SV, AS, TA: Conception/design of the protocol, data analysis/interpretation, critically reviewing the paper, and approving the final version to be published. AK, RTS, VS, KM, BVSSKT: Acquisition of data, critically reviewing the paper, and approving the final version to be published. SV, AS, RK: Role of mentor/senior investigator during conception, design, acquisition of data, critically reviewing the paper, and giving approval for the final version to be published.

Ethical approval

Ethics approval was obtained from the Institution Review Board, CCHRC, Silchar, India (ECR/925/Inst/AS/2017/RR-21), dated 13 April 2024.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Modules 1 and 2 of the SORT IT course were conducted virtually over the eSORT IT platform (https://www.sortitresearch.com/en). Module 3 was conducted in person at CCHRC Silchar, India. The CMOG, Chennai, India, and CCHRC Silchar, India, supported the training programme costs for Module 3.

Conflicts of interest

There are no conflicts of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation

The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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