Effect of Postsurgical Nurse-led Follow-ups on Quality of Life in Head-and-Neck Cancer Patients: A Pilot Randomized Controlled Trial

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Abstract

Objective: Burden of head-and-neck cancer is disproportionately bigger in India and can be regarded as “tip of iceberg” situation. Postoperatively, head-and-neck cancer patients report tremendous challenges conversely, affects quality of their life. Oncology nurses contribute significantly in supportive care issues encountered by patients in the postoperative period. However, there is a paucity of the literature on effect of nurse-led postsurgical education program on quality of life (QOL) of head-and-neck cancer patients. Methods: In this pilot randomized controlled, parallel group trial, 64 head-and-neck cancer patients; who were electively planned for surgery were randomized in experimental (n₁ = 32) and control group (n₂ = 32). In the experimental group, participants received structured nurse-led postsurgical education program through virtual mode and control group participants received standard of care. The QOL as an outcome variable was assessed through face-to-face interview at baseline on first postoperative day and postoperative day-4, 15, and 30 follow-ups by using standardized instruments, i.e., EORTC QLQ-C30 and H and N35 questionnaire. Results: The experimental group had a significant improvement in global health (P = 0.02), role functioning (P = 0.02), emotional functioning (P = 0.01), swallowing (P = 0.01), and opening mouth (P = 0.02). Postoperative pain and speech problems were most distressing symptoms in participants of both groups. Conclusions: The nurse-led postsurgical virtual education programme was found effective to improve the selected domains of QOL and may be used as an adjuvant intervention for head-and-neck cancer patients.

Key words: Head-and-neck cancer, nurse-led post-surgical education program, quality of life

Introduction

Head and neck cancer are diversified group of diseases, encompassing tumors of lip, oral cavity, hypopharynx, nasopharynx, and larynx. Worldwide, it represents 0.65 million cases and 0.33 million deaths annually.[1] Furthermore, in India, the burden of cancer is disproportionately bigger accounting the incidence of 1.75 lakhs annually with 76% affected males.[2-4]

Despite of having numerous treatment options, surgery is the mainstay neoadjuvant treatment for head and neck cancer patients. The patients are operationally and functionally impaired with surgery.[5] Postoperatively, a significant deterioration in physical and psychological quality of life is often noted.[6] A positive outcome of surgery is dependent on the co-ordinated support provided by healthcare professionals. Since, surgery can result in life-threatening conditions, extensive support is often required to facilitate patients’ functional rehabilitation[7] and psychosocial adjustments.[8]

Nursing supportive interventions are effective in improving surgical outcomes of head and neck cancer patients.[9] However, the impact of nurse-led education program for head and neck cancer patients was not well studied.

The objective of this randomized controlled trial was to evaluate the impact of a structured nurse-led follow-up program designed specifically for head and neck cancer patients on quality of life (QOL) compared to standard care.
cancers. However, postsurgically, patients experience additional physiological and psychological distress such as pain, dysphagia, and esthetic concern that can further hamper their quality of life (QOL).\cite{5-7} QOL is a subjective and comprehensive assessment of state of life and considered as an important indicator for evaluating health care outcomes.\cite{8}

Need for self-care information by patients dictating the emergence of innovative ways of nursing interventions. Oncology nurses contribute significantly by using various supportive media technologies (WhatsApp) for educational purposes to meet postoperative challenges and provide comprehensive care. There is a paucity of regional data of QOL among head-and-neck cancer patients and also the use of media technologies as a novice educational tool. The increasing number of head-and-neck cancer cases is a major cause of their mortality and morbidity which affects their QOL. After cancer-directed treatment (surgery, radiotherapy, and chemotherapy), mean score in QOL was declined, mainly in global health status\cite{9} (2020), emotional function (2020)\cite{6} and in symptom scales: pain, swallowing, speech, and mouth problems (2020),\cite{6} financial difficulties, insomnia, and diarrhea\cite{9} appearance, swallowing, chewing, speech, shoulder pain and discomfort, taste and saliva production scores (2014).\cite{7} Patients with an advanced stage (3 and 4) had high symptomatology and worse QOL score as compared to earlier stage (1 and 2).\cite{8} Major problems associated with advanced stage were limited mouth opening, pain, speech problems, appearance issues, and increased anxiety.\cite{5}

**Methods**

**Trial design**

This prospective, randomized, controlled, parallel group trial with treatment allocation 1:1 was conducted to assess the effect of nurse-led postsurgical education program on QOL. Ethical permission was obtained from the Institutional Ethics Committee of All India Institute of Medical Sciences vide letter no. AIIMS/IEC/19/606. Trial was prospectively registered with the Clinical Trials Registry, number CTRI/2019/10/021617. Participants were informed about the purpose, and they were ensured about anonymity and confidentiality of the information. An informed written consent was obtained from every participant.

**Participants**

During the study period, a total of 64 head-and-neck cancer patients (exp = 32; control = 32) who were planned for elective surgery and admitted in the department of surgical oncology during month of October 2019–February 2020 were recruited in the study. Patient aged ≥18 years, planned for elective surgeries, understand Hindi or English, had smartphone with self or family member were included in the present study. However, patients who were critically-ill and had psychopathologies were excluded from the study [Figure 1].

In the reference of previous study, sample size was estimated using the following formula \( n = 2 \times K(\sigma/\mu_1–\mu_2)^2 \) where, \( \mu_1 = 70, \mu_2 = 82 \), with an absolute error of 5%, confidence interval 95%.\cite{10} Thus, a sample of 64 eligible participants, who met the inclusion and exclusion criteria were recruited for this pilot trial.

**Intervention**

**Planning**

Formation of draft for nurse-led postsurgical education program was done by focused group interview with 10 head-and-neck cancer patients to understand prioritized needs, literature searches and expert opinion was taken and incorporated into prepare an informational professional video.

**Nurse-led postsurgical programme content**

Main areas in which program emphasized, were swallowing exercise, nutritional counseling, and pain management. The total duration of video was 12 min.

- Swallowing exercises mainly included jaw mobility exercise, tongue mobility exercises (tongue protrusion, tongue elevation, and depression and tongue lateralization), airway protection, hyolaryngeal excursion and tongue base exercise (the Masako exercise), gargle without use of water, yawn, and the shaker exercises. Time duration of content was 4 min
- Nutritional counseling emphasized on feeding through nasogastric tube, how to get rid of weight loss, appetite loss, ulcer and constipation, and use of baking soda gargle. Time of content was 6 min
- Pain counseling focused mainly on nonpharmacological approach and guidelines to be followed for taking medicines. Time of content was 1 min and 30 s

Video validation was done by 9 experts of department of surgical oncology and medical surgical nursing. After preparation of draft, video was delivered to four head-and-neck cancer patients for content understanding.

**Implementation**

After collection of baseline data, 20-min focused, face to face nurse-led postsurgical education on holistic postoperative care was provided to participants in the experimental group by using virtual teaching tools at preoperatively and postoperative on day-4 in a separate room of surgical oncology ward.
During discharge, educational video was sent on their smartphone through WhatsApp and telephonically follow-ups were done on every 7th day. Assessment of QOL was done at postoperative day 4 and postoperative follow-up day 15 and day 30.

The participants in the control group received standard nursing care including nursing assessment and patient care such as patient monitoring, basic care of all patients, which includes meditation and head and neck exercise in the preoperative period.

**Outcome measure**

The primary outcome of the study was “quality of life” among head-and-neck cancer patients. QOL was measured with the European Organization of Research Treatment of Cancer QOL Questionnaire and with head-and-neck cancer module version 3.0 (EORTC QLQ-C30 and QLQ-H and N35).

Data were collected through a 15–20-min face-to-face interview with each participant using standardized and reliable tools, as detailed below.
Semi-structured questionnaire was prepared to assess the sociodemographic and clinical profile of participants.

i. EORTC QLQ-C30 is a standardized; a Likert response questionnaire, which consists 30-items. It is divided into three domains: global health (2), functional scales (15), and symptom scales (13) that measure overall QOL. Each item has a Likert response scale and the response is categorized into four scores from very much (4), to not at all (1) except in 2 statements of global health status, scoring from 1 to 7, where 1 indicate worse condition health and 7 represent good health.

ii. EORTC QLQ H and N 35 contains 35 items which includes 7 multi-item and 11 single-item scales to assess symptoms: pain, swallowing, teeth, opening mouth, dry mouth, sticky saliva, coughing, felt-ill, senses, speech, social contact, social eating, nutritional status, feeding tube, weight loss, and weight. Each item has a Likert response from 1 to 4, where 1 = not at all 2 = a little 3 = quite a bit 4 = very much.

The scoring of EORTC tools was done according to EORTC manual by calculating raw score (RS) and linear transformation in 0-100. RS is calculated by average of the items.

- Functional Scales, $S = (1-\{(RS-1)/range\}) \times 100$
- Symptom scale, $S = (RS-1)/range \times 100$
- Global health status, $S = (RS-1)/range \times 100$

Range is the difference between the maximum possible value and the minimum possible value. High score for a functional scales and global health represents a high or good level of functioning, but high score for a symptom scales represents a high level of symptomatology or problems.

Although tools were standardized, due to change in patient setting reliability of tools were calculated by internal consistency (Karl Pearson correlation co-efficient) and found 0.70 and 0.76, respectively. Tools permission was taken from EORTC QOL group website.

Randomization and allocation

In this pilot trial, block randomization (block size of 4) technique with 1:1 treatment allocation was used. The randomization plan was generated with the help of online resource (Sealedenvelope.com) along with unique codes for each participant. Allocation concealment of the treatment was done with the help of the pre-determined sequences written on paper slips and was kept in the sealed opaque envelopes. Each envelope had unique code written and arranged sequentially as per randomized list. Primary investigator collected opaque envelope from third person, who had prepared the envelop using pregenerated block random numbers. After obtaining informed written consent, opaque-sealed envelope was opened and assigned to either treatment or control group based on that assignment. It was an open trial; therefore, neither patient nor researcher was blinded.

Statistical analysis

Data were coded and then entered to Excel sheets and Statistical Package for the Social Sciences software (SPSS 23.0), developed by Norman H. Nie, C. Hadlai Hull and Dale H. Bent in 1968 at University of Stanford, was used for the statistical analysis. Descriptive and inferential statistics were used for the data analysis. Sociodemographic characteristics and participants’ clinical profile were presented using frequency and percentage, while comparison of QOL was done using mean and standard deviation. Mann-Whitney test was used to compare of QOL among experimental and control group, whereas mixed model analysis was used to determine the mean differences at 0.05 level of significance.

Results

A total of 60 participants (52 males and 8 females) were analyzed. The participants in both experimental and control group were homogenous as per age (48.9 ± 9.6 vs. 49.3 ± 11.6 years), suffering from oral cancer (93% vs. 90%) and surgery as treatment (97% vs. 94%), and presented with stage 3 (73% vs. 67%), history of alcohol intake (53% vs. 47%), and history of tobacco use (73% vs. 70%), respectively, as shown in Table 1.

More than half (>50%) of participants in experimental and control group were using home-brewd alcohol (56% vs. 64%), followed by wine (44% vs. 36%). Similarly, among tobacco consumers, more than half were using noncombustible products (55% vs. 62%), followed by combustible products (45% vs. 38%). Moreover, among combustible products, most of them (80% vs. 88%) were using bidi, followed by cigarettes (20% vs. 12%) respectively. Furthermore, among noncombustible products, all of them were using chewing tobacco (100%) in both groups.

Mann–Whitney test was used to compare QOL with participant’s global health status, functional scales, and symptoms scales and result revealed that at time point $T_1$ (30th day), experimental group showed significantly improvement in role functioning ($P = 0.02$) and pain score ($P = 0.01$) as compared with $T_1$ (baseline) and $T_1$ (15th day) [Table 2]. According to head and neck specific QOL of symptom, the results revealed that at $T_1$ (30th day), swallowing ($P = 0.01$) and opening mouth ($P = 0.02$) showed a significant improvement in the experimental group [Table 3].

Mixed model analysis was used to reflect the change in the mean score of QOL from $T_1$ (postoperative 4th day) to $T_2$ (15th day) and $T_2$ (30th day). It was found that at $T_3$ experimental group significantly improved for role functioning (9.4, 95% confidence interval [CI]: 2.5-16.3) as
compared to the control group ($P = 0.008$). At $T_4$, significant differences were found for global health (6.66, 95% CI: 1.5–11.7, $P = 0.01$) and role functioning (6.3, 95% CI: 0.8–11.8, $P = 0.02$). At $T_4$, in symptom scales, experimental group reported significantly fewer problems with opening mouth (−12.2, 95% CI: −23.9–−0.5, $P = 0.04$) and use of painkiller (30.0, 95% CI: −56.0–−3.8, $P = 0.02$) [Table 4].

**Discussion**

As QOL is broad, long-term and multidimensional concept, assessment must be done frequently in postoperative follow-ups to find tremendous challenges patient is facing. Patient education and follow-ups, preferably in the preoperative and postoperative period have a major role in significantly improvement in QOL, so that patients can more successfully adapt to the changes due to the effect of treatment. Oncology nurse specialist significantly contributing in multidisciplinary care to alleviate symptoms and providing supportive follow-up care. Some literatures suggested the potential impact of this care in quality improvement; however, there is a paucity of sound researches. [11]

In the present study, nurse-led postsurgical education had a positive impact on QOL in the experimental group and more relevant changes were observed at postoperative
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### Table 2: Comparison of quality of life score in experimental and control group at baseline (T₁), follow-up day 15 (T₂) and day 30 (T₃)

| Variables                   | Baseline preoperative (T₁) | Follow-up day 15 (T₂) | Follow-up day 30 (T₃) |
|-----------------------------|---------------------------|------------------------|------------------------|
|                             | Mean±SD (Experimental (n=30)) | Mean±SD (Control group (n=30)) | Mean±SD (Experimental (n=30)) | Mean±SD (Control group (n=30)) | P   |
| Global health               | 75.8±7.0                  | 77.1±7.2               | 70.2±6.4               | 68.0±7.9               | 0.36 |
| Functional scales           |                           |                        |                        |                        |     |
| Physical functioning        | 95.6±16.4                 | 91.1±23.0              | 95.9±4.7               | 93.0±5.5               | 0.08 |
| Role functioning            | 98.3±5.0                  | 96.1±7.1               | 88.3±9.9               | 82.1±10.6              | 0.02*|
| Emotional functioning       | 88.3±4.7                  | 88.2±5.1               | 78.0±6.3               | 76.9±5.1               | 0.42 |
| Cognitive functioning       | 98.8±4.2                  | 99.4±3.0               | 79.9±11.0              | 82.7±11.9              | 0.36 |
| Social functioning          | 98.8±4.2                  | 98.3±6.7               | 86.6±9.1               | 84.4±11.5              | 0.45 |
| Symptom scales              |                           |                        |                        |                        |     |
| Fatigue                     | 6.1±6.0                   | 3.9±5.9                | 26.8±8.9               | 23.7±7.7               | 0.17 |
| Nausea and vomiting         | 0.5±3.0                   | 0.0±0.0                | 0.5±3.0                | 0.5±3.0                | 1.00 |
| Pain                        | 26.6±11.2                 | 22.7±8.1               | 31.0±9.5               | 37.4±10.4              | 0.01*|
| Dyspnea                     | 3.3±10.9                  | 1.1±6.7                | 11.6±6.0               | 2.2±8.4                | 0.55 |
| Insomnia                    | 6.6±13.5                  | 5.5±12.6               | 15.5±19.0              | 16.6±16.9              | 0.70 |
| Appetite loss               | 19.9±18.7                 | 21.0±16.3              | 17.7±19.0              | 15.5±19.0              | 0.62 |
| Constipation                | 1.1±6.0                   | 0.0±0.0                | 3.3±13.4               | 3.3±10.1               | 0.67 |
| Diarrhea                    | 0.0±0.0                   | 0.0±0.0                | 1.1±6.0                | 3.3±10.1               | 1.00 |
| Financial difficulties      | 9.9±17.8                  | 8.8±19.4               | 14.4±16.7              | 15.5±20.9              | 0.97 |

*Significant at P<0.05; NSNS at P>0.05. SD: Standard deviation; NS: Not significant

### Table 3: Comparison of head and neck specific quality of life at baseline (T₁), follow-up day 15 (T₂) and day 30 (T₃) (n=60)

| Variables                   | Baseline preoperative (T₁) | Follow-up day 15 (T₂) | Follow-up day 30 (T₃) |
|-----------------------------|---------------------------|------------------------|------------------------|
|                             | Mean±SD (Experimental (n=30)) | Mean±SD (Control group (n=30)) | Mean±SD (Experimental (n=30)) | Mean±SD (Control group (n=30)) | P   |
| Symptom scales              |                           |                        |                        |                        |     |
| Pain                        | 16.0±5.7                  | 18.5±5.2               | 11.9±4.7               | 12.7±5.2               | 0.55 |
| Swallowing                  | 3.8±5.2                   | 4.2±4.3                | 21.6±2.5               | 23.3±5.5               | 0.23 |
| Teeth                       | 0.4±1.5                   | 1.1±6.0                | 0.0±0.0                | 0.0±0.0                | 1.00 |
| Opening mouth               | 33.3±24.7                 | 37.7±16.8              | 46.6±16.5              | 52.1±16.7              | 0.24 |
| Dry mouth                   | 12.2±16.3                 | 6.6±13.5               | 13.3±16.5              | 17.7±16.8              | 0.30 |
| Sticky saliva               | 4.4±11.5                  | 2.2±8.4                | 28.8±19.0              | 22.2±22.0              | 0.17 |
| Senses                      | 3.6±5.2                   | 2.2±5.7                | 4.4±7.4                | 6.6±13.5               | 0.90 |
| Coughing                    | 2.2±8.4                   | 1.1±6.0                | 17.7±20.9              | 17.7±22.6              | 0.90 |
| Felt ill                    | 9.9±17.8                  | 12.2±22.2              | 27.7±21.5              | 26.6±20.3              | 0.86 |
| Speech                      | 3.6±5.2                   | 5.5±5.5                | 34.3±8.8               | 36.6±8.7               | 0.31 |
| Social eating               | 2.7±6.2                   | 2.2±5.7                | 1.3±3.1                | 2.2±4.3                | 0.45 |
| Social contact              | 1.6±3.3                   | 0.4±1.5                | 1.6±2.6                | 1.6±2.6                | 1.00 |
| Pain killer                 | 86.6±34.5                 | 76.6±43.0              | 66.6±47.9              | 46.6±50.7              | 0.12 |
| Nutrition supplements       | 90.0±30.5                 | 83.3±37.9              | 100.0±0.0              | 100.0±0.0              | 1.00 |
| Feeding tube                | 6.6±25.3                  | 0.0±0.0                | 100.0±0.0              | 100.0±0.0              | 1.00 |
| Weight loss                 | 36.6±49.0                 | 56.6±50.4              | 26.6±44.9              | 33.3±47.9              | 0.57NS|
| Weight gain                 | 3.3±18.2                  | 11.9±65.4              | 16.6±37.9              | 13.3±34.5              | 0.72NS|

*Significant at P<0.05; NSNS at P>0.05. SD: Standard deviation; NS: Nonsignificant

The present study result showed that all the patients (100%) experienced decline in global health status in the postoperative period at 15th day, conversely significant improvement seen at the 30th day in the experimental (90.7 ± 6.3) as compared to the control group (85.2 ± 6.8) which is in conformity with the findings of follow-up day 30 in the experimental group as compared to the control group, although effects were not statistically significant. Furthermore, other research findings were based on long-term follow-ups, whereas present study findings were based on 1-month follow-up, still there was improvement in domains of QOL.
of the study conducted at long-term follow-ups by Van der Meulen et al.\textsuperscript{[12]} and De Leeuw et al.\textsuperscript{[11]} reported psychosocial intervention and nurse-led follow-up improved global health status in intervention group ($P < 0.05$).

Furthermore, our result showed that there was improvement in functional scores at follow-up day-30, mainly role functioning ($88.3 \pm 9.9$ vs. $82.1 \pm 10.6$) and emotional functioning ($98.8 \pm 4.2$ vs. $96.9 \pm 4.1$) were significantly improved in the experimental group as compared to the control group, respectively. These results were consistent with another study van der Meulen et al.\textsuperscript{[12]} Senchak et al.\textsuperscript{[13]} Shi et al.\textsuperscript{[14]} where nursing intervention had beneficial effect on physical, emotional, and role functioning and were better in the intervention group.

Postoperatively, symptoms such as pain ($31.0 \pm 9.5$ vs. $37.4 \pm 10.4$), opening mouth ($12.2 \pm 16.3$ vs. $22.2 \pm 15.9$), and swallowing ($11.6 \pm 4.1$ vs. $15.2 \pm 5.4$) were significantly improved, whereas speech concern was most distressing factor and had interference with QOL, where mean pain score was $15.1 \pm 5.4$ vs. $17.7 \pm 6.9$ in the experimental group as compared to the control group, respectively. Result showed that nurse-led postsurgical program, especially exercises and motivation to adhere to program help them to control symptoms such as opening mouth and swallowing. Similar findings results are in support with the findings of another studies Senchak et al.\textsuperscript{[13]} Shi et al.\textsuperscript{[14]} Hansson et al.\textsuperscript{[15]} in which pain and swallowing trouble and limited mouth opening were lower in the intervention group as compared to the control group.

**Limitations**

1. Study was confined to a single center only

2. Small sample size ($n = 64$)

3. Effect of intervention within 1-month postoperative may underestimation the effectiveness.

**Conclusions**

In general, QOL become worse after cancer-directed treatment and impacts QOL of patients. Postoperative complications have significant interference with global health, functional score, and symptoms scores. Oncology nurses can contribute significantly in further development and advancement of follow-up care for head-and-neck cancer patients. In the present study, nursing educational program had significant effect on patient’s global health, role and emotional functioning, swallowing, and opening mouth. Therefore, it is recommended that an adjunct nurse-led postsurgical education program should be included in the care of head-and-neck cancer patients to improve overall QOL of patients with cancer.

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**Conflicts of interest**

There are no conflicts of interest.

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