Published online: 2021-07-12

ORIGINAL ARTICLE

Comparison of postoperative complications in advanced head and neck cancer patients receiving neoadjuvant chemotherapy followed by surgery versus surgery alone

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ABSTRACT

Background: Head and neck cancer is the third most common cancer in India with 60% presenting in advanced stages. There is the emerging role of neoadjuvant chemotherapy (NACT) in the management of these advanced cancers. There is a general perception that complication rates are higher with the use of NACT. **Materials and Methods:** This is a retrospectively collected data of head and neck cancer patients operated at our hospital from March 2013 to September 2014. A total of 205 patients were included in the study. These patients were studied in two groups. Group 1 included 153 patients who underwent surgery alone, and Group 2 included 52 patients who received 2-3 cycles of NACT followed by surgery. **Results:** The mean age of the population was 51 years in the Group 1 and 45 years in Group 2. The hospital stay and readmissions in postoperative period were similar in the two groups. In this study, the complication rate was 37.9% in the surgery patients and 30.8% in the NACT patients (P = 0.424). **Conclusion:** The postoperative complication rates in patients who received NACT followed by surgery were not significantly different from those who underwent surgery.

Key words: *Complications, head and neck cancer, neoadjuvant chemotherapy, surgery*

INTRODUCTION

Head and neck cancer is the third most common cancer in India with 60% presenting in advanced stages.[1,2] The prognosis depends upon the stage of the disease. Early stage cancers have 5 years survival of 80-90%. Advanced stage cancers have a poor prognosis with 5 years survival of 25-50%.[3]

Surgery for nonmetastatic advanced head and neck cancer is an important prognostic marker.[4] Complete surgical resection of the tumor with free margins remains an important goal. Management of advanced cancers involves multidisciplinary treatment, but guidelines are not defined for very advanced cancers. There is the emerging role of neoadjuvant chemotherapy (NACT) in these advanced cancers.

NACT is useful in reducing the tumor volume and thus making unresectable tumors resectable.[4,5] It may be helpful in organ preservation and thus avoiding complex morbid surgeries with functional disabilities.[6] NACT is useful in assessing tumor response to chemotherapy, selecting appropriate local treatment and improving survival. It has a theoretical benefit in control of micrometastasis, thus improving local and systemic control.[7-11] We routinely use neoadjuvant at our center for locally advanced head and neck cancers, when it is questionable to achieve free margins of resection following surgery.[4]

Various factors play a role in wound healing in the postoperative period in cancer patients. These include nutritional status, disease stage and the type of treatment planned. Radiation therapy is known to impair wound healing when doses larger than 50 Gy are given, or radiotherapy is given <3 weeks before surgery.[7-13] The toxicity associated with NACT can contribute to postoperative mortality and morbidity. However, most of the studies have shown that NACT does not increase postoperative morbidity.[14-18] There are no similar studies in head and neck cancers. The aim of this study was to

Access this article online

Quick Response Code:

Website: www.ijmpo.org

DOI: 10.4103/0971-5851.171548

How to cite this article: Joshi P, Joshi A, Prabhash K, Noronha V, Chaturvedi P. Comparison of postoperative complications in advanced head and neck cancer patients receiving neoadjuvant chemotherapy followed by surgery versus surgery alone. Indian J Med Paediatr Oncol 2015;36:249-54.

find out if the use of chemotherapy was associated with increased complications in the postoperative period.

MATERIALS AND METHODS

This is a retrospectively collected data of head and neck cancer patients operated at our hospital from March 2013 to September 2014. The aim was to compare complications and mortality in first 30 days in the postoperative period between patients receiving NACT followed by surgery and those treated with surgery alone in head and neck cancer. A total of 205 patients were included in the study. The data were collected from the electronic medical record of the hospital.

Since this was a retrospective collection of data, we divided patients into two groups depending upon whether patients received NACT followed by surgery or upfront surgery without NACT. Group 1 included 153 patients who underwent surgery immediately after diagnosis, and Group 2 included 52 patients who received 2-3 cycles of NACT followed by surgery. Cases were selected based on the following eligibility criteria:

1. Biopsy confirmed squamous cell carcinoma of oral cavity, larynx and hypopharynx,
2. Treatment naïve patients, and
3. All T4 primary tumors.

The reasons for giving NACT in these groups of patients included edema reaching up to zygoma in buccal mucosa-alveolus complex lesions, tongue cancers close to mandible, extensive exolaryngeal disease in soft tissues of neck in carcinoma of larynx, and hypopharynx.

The complete preoperative evaluation was done in all patients including examination under anesthesia, direct laryngoscopy, imaging with contrast enhanced computed tomography scans; magnetic resonance imaging or positron emission tomography scans whenever indicated.

The primary objective of the study was to assess the difference in complication rates between Groups 1 and 2. The NACT drug regimens used included two or three drug chemotherapy. NACT was given as two drug regimen with 3 weekly regimens of cisplatin and docetaxel as 75 mg/m^2 each on day 1 or three drug regimen with 5-flurouracil as 750 mg/m^2 as 24 h intravenous infusion for 5 days for 3 cycles along with cisplatin and docetaxel. Patients receiving three drug regimens were given granulocyte-colony stimulating factor prophylactically from day 6 to day 12. Tablet levofloxacin 500 mg once daily was given for the same duration as a primary prophylaxis for bacterial infections.

Forty-one patients received two drug regimen and 11 patients received three drug regimen. Carboplatin as AUC 6 was given to those with compromised glomerular filtration rate of <60 ml/min. The reasons for using two drug regimens in the majority of the patients were logistic reasons, economical constraints, and comorbidities.

The complication details were grouped as a major and minor complications. Major complications were those in which surgical intervention was needed; patients were re-hospitalized or hospitalized for more than 14 days. Minor complications were defined as those in which conservative management was followed.

Statistical methods used

Statistical analysis was done using the software SPSS version 20.0 (IBM, NY, USA). Calculation of values was done in percentages. The various tests used in the study included Chi-square test for univariate analysis, Wilcoxon signed-rank test, test for the median, unpaired *t*-test, and Mann-Whitney test.

RESULTS

The mean age of the population in the Group 1 was 51 years, and Group 2 had a younger population with a mean age of 45 years with a significant difference in *P* value. The majority of the patients were males and had an oral cavity (93%) as the major subsite with no statistical difference between the two groups. Fifty-one percent patients in Group 1 and 46% patients in Group 2 had pathological N+ (node positive) status. Nearly ¼ of the patients (24%) in Group 1 and 15.6% patients in Group 2 had comorbidities ($P = 0.21$) as shown in Table 1. The patients did not differ in terms of comorbidities in the two groups.

The mean (and median) value of hemoglobin and albumin was higher in Group 1 as compared to Group 2 ($P < 0.05$). The preoperative and postoperative absolute neutrophil count (ANC) was similar in both the groups with ($P = 0.65$) as shown in Table 2.

The types of surgeries performed included buccal mucosa/mandible composite resections, total laryngectomy, infrastructure/orbital plate preserving/total maxillectomy, and wide excision of tongue/near total/total glossectomy procedures. Neck dissections were performed in 202 patients and 3 patient's neck were not addressed. Modified neck dissection was performed in 151 patients, selective neck dissection (I-IV, I-III, II-IV) in 48 patients, and radical neck dissection in 3 patients. Reconstruction was done with primary closure/local flaps/skin grafts in 31 patients, pedicle flap like PMMC in 112 patients and free flaps such as FRAFF, FFOCF, and FALT in 62 patients.

Fifty-eight patients (37.9%) in Group 1 had complications. Thirty patients had major, and 28 patients had minor complications. Sixteen (30.7%) patients in Group 2 had complications. Six patients had major, and 10 patients had minor complications. Major complications included

Table 1: Demographic details

Demographic variables	Surgery *n* = 153 (%)	Neoadjuvant chemotherapy *n* = 52 (%)	*P*
Age (years)			
Mean	51 (11.96)	45 (9.77)	0.001
Median	50	44	0.001
Range	29-76	25-70	
Sex			
Male	129 (84.3)	43 (82.7)	0.78
Female	24 (15.7)	9 (17.3)	
Site			
Oral	142 (93)	48 (92.3)	0.90
Pharynx	8 (5)	3 (5.8)	0.88
Larynx	3 (2)	1 (1.9)	0.98
Nodal status (pathological)			
No	73 (47.7)	27 (51.9)	0.368
N+	78 (50.9)	24 (46.1)	
NA (not addressed)	2 (0.01)	1 (0.19)	
No	73	27	
N1	27	03	
N2a	11	03	
N2b	39	13	
N2c	08	02	
N3	04	03	
NA (not addressed)	02	01	
Comorbidities			
Yes	36	8	0.21
No	117	44	
Diabetes	9 (5.9)	2 (3.8)	
Hypertension	9 (5.9)	3 (5.8)	
Cardiac	1 (0.7)	0	
Diabetes + hypertension	9 (5.9)	1 (1.9)	
Pulmonary	7 (4.6)	1 (1.9)	
Others	1 (0.7)	1 (1.9)	
None	117 (76.47)	44 (84.6)	

Table 2: Laboratory and biochemical details

Blood investigations	Surgery *n* = 153 (%)	Neoadjuvant chemotherapy *n* = 52 (%)	*P*
Hemoglobin (g/dl) (preoperative)			
Mean	12.75	11.67	0.00
Median	13.1	11.65	0.00
Range	7.4-18.7	7.6-15.2	
Absolute neutrophil count (10^9/L) preoperative			
Mean	5.61	5.4	0.65
Median	4.83	4.73	0.78
Range	2.37-24.8	1.43-17.95	
Absolute neutrophil count (10^9/L) postoperative			
Mean	9.89	9.36	0.50
Median	9.23	8.25	0.25
Range	2.43-37	2.92-36.9	
Albumin (g/dl) preoperative			
Mean	4.25	3.84	0.00
Median	4.29	3.9	0.00
Range	2.56-10.5	1.62-4.64	

flap necrosis, hematoma evacuation, nerve injury and others, and minor complications included seroma collection, salivary fistula leak and nerve paresis as shown in Table 3.

The antibiotics used at our hospital in the postoperative period are the third generation cephalosporins. In case of infection such as flap necrosis, fistula communicating oral cavity to neck, and collection in neck/collection beneath the flap, prolonged antibiotics were given (for more than 7 postoperative days). Twenty-seven patients (17.6%) had an infection in Group 1 and 25 were given prolonged antibiotics. Change to higher generation antibiotics was done in 24 patients. The higher antibiotics included a combination of cefoperazone and amikacin and piperacillin-tazobactam depending upon the culture-sensitivity. In Group 2, 5 (9.3%) patients had an infection with the change to higher antibiotics in all 5 patients.

Six (4%) patients in Group 1 had hemorrhage in the postoperative period, and only 1 patient (1.9%) in Group 2 had hemorrhage. Exploration was done in 15 (9.8%) patients in Group 1 for hematoma evacuation, seroma, chyle leak, and flap failure. Six explorations were done in Group 2 for flap necrosis and hematoma evacuation. Various other complications such as hypotension, hyponatremia, and arrhythmias were seen in other patients, as shown in Table 3.

Most of the patients included in the study were advanced stage tumors. Preoperatively, one patient was inoperable in Group 1 and 2 were inoperable in Group 2. There were no deaths peri operatively. The operative time was ≥4 h in the majority of the cases in both the groups ($P = 0.098$). The hospital stay and a number of readmissions in postoperative period were similar in the two groups (*P* insignificant). The mean blood loss in the first group was 698 ml as compared to 906 ml in the second group as shown in Table 4.

This needs to be taken with caution since in Group 2 the data were available in 29 patients only ($P = 0.11$). Hence, this could be misleading due to small sample size of the patients.

DISCUSSION

The treatment of head and neck cancers involves resection of the tumor with wide margins and regional lymph node dissection. Resection in advanced cancers is associated with significant morbidity. There has been an increasing trend for the use of NACT in advanced head and neck cancers in the last decade. This was after the promising data showing the benefit of NACT in reducing the tumor volume, and organ preservation was published.[19]

Table 3: Complication details

Complications	Surgery *n* = 153 (%)	Neoadjuvant chemotherapy *n* = 52 (%)	*P*
Major complications	30 (19.6)	6 (11.5)	0.424
Minor complications	28 (18.3)	10 (19.2)	
None	95 (62.09)	36 (69.2)	
Major			
PMMC flap/free flap/neck skin necrosis	12	5	
OCF	8		
Hematoma evacuation	6	1	
Preoperative spinal accessory nerve/facial nerve injury	2		
Arrhythmia	1		
DVT	1		
Minor			
Seroma	6	3	
Chyle leak	4	1	
Salivary fistula	7	4	
Marginal nerve paresis	5	1	
Wound erythema/dehiscence	2		
Hypotension per operatively	1		
Hypocalcemia/hyponatremia	2	1	
Fever	1		
Infection			
Yes	27 (17.6)	5 (9.4)	0.08
No	126 (82.4)	48 (90.6)	
Change of antibiotics			
Yes	24 (16.6)	5 (10.4)	0.27
No	129 (83.4)	47 (89.6)	

DVT – Distal vein thrombosis; OCF – Orocutaneous fistula; PMMC – Pectoralis major musculocutaneous

Table 4: Mean hospital stay and readmissions

Peri operative parameters	Surgery *n* = 153 (%)	Neoadjuvant chemotherapy *n* = 52 (%)	*P*
Readmissions (*n*)			
No	135 (88.2)	41 (78.9)	
Yes	18 (11.8)	11 (21.1)	0.09
1	16 (10.5)	10 (19.2)	
2	1 (0.7)	1 (1.9)	
3	1 (0.7)	0	
Postsurgery hospital stay in days			
Mean	11	11	
Median	8	8	0.162
Range	2-37	3-40	
Blood loss (ml)	*n*=152	*n*=29	
Mean	698	906	
Median	650	800	0.11
Range	50-2000	50-3000	
Intraoperative events (inoperability/death)			
Uneventful	152 (99.3)	50 (96.2)	0.097
Eventful	1 (0.7)	2 (3.8)	
Duration			
≥4 h	123 (80.4)	47 (90.4)	0.098
<4 h	30 (19.6)	5 (9.6)	

Multiple experimental studies on animals have shown that chemotherapy drugs target rapidly dividing cells and thus cause apoptosis of tumor cells. But, the normal dividing cells like macrophages and fibroblasts are also susceptible. This affects the inflammatory phase delaying the wound healing.[20] This hypothesis suggests that we should have a more infective complication in the postoperative period, but infection rates were similar in both the arms. It is possible that patients after chemotherapy may have improvement in symptoms related to cancer which may result in better nutritional intake and thus lesser negative impact on immunity.

ANC has high sensitivity in detecting acute bacterial infections.[21] In this study, values below or above the normal range (2.0-7.0 × 10^9/L) were considered abnormal with the higher risk of infection. The mean preoperative ANC value was 5.6 × 10^9/L in Group 1 and 5.4 × 10^9/L in Group 2. The mean postoperative values ANC values were high (>7.0 × 10^9/L) in both the groups with no difference statistically. Thus, patients who received NACT did not have abnormal ANCs as compared to surgery group and hence no higher risk of infection.

Alkylating agents such as cyclophosphamide, cisplatin and antimetabolites such as methotrexate, 5-fluorouracil decrease wound tensile strength and impede wound healing during the early proliferative phase in animal studies.[22,23] However, most of the studies on humans have shown no increased risk of wound complications or delayed healing with neoadjuvant and adjuvant chemotherapy at therapeutic doses.[24,25] In our patients, we used taxanes with platinum. It is possible that there is the differential impact on wound healing by different drugs.

The meta-analysis of NACT in esophageal carcinoma,[14] gastric carcinoma,[15] and bladder carcinoma[17] has shown that there was no difference in rate or severity of preoperative or postoperative complications post-NACT. NACT did not prevent patients from undergoing cystectomy for bladder cancers[17] and was associated with a 6.5% absolute benefit in 5-year overall survival.[26]

Patients in the Group 1 (surgery) were older than those in Group 2 ($P = 0.001$). For analysis purpose, patients in both groups were divided according to age into those with age >65 years or ≤65. But patients with age >65 were not associated with the development of postoperative complications or longer hospital stay when compared with those with age ≤65 (*P* value not significant).

The numbers of readmissions and preoperative events were the same in the two groups. The mean hemoglobin level and albumin levels which are indicators of the nutritional status of the patient showed higher values in Group 1 (surgery) as compared to Group 2 (NACT). This could be due to larger tumors being given NACT, which had

functional difficulty in swallowing. However, this did not reach a value of statistical significance.

Our study showed that the mean preoperative blood loss associated with Group 2 (NACT) was higher as compared to Group 1 (surgery). However, the blood loss was available in only 56% of patients in Group 2. Thus, it is difficult to infer the association of NACT with blood loss with our study. Most of the studies in the literature show no increased blood loss with the use of chemotherapy.[27,28]

The main limitation of the study was that it was a retrospective study. Retrospective studies always have their inherent biases. The details of blood loss were missing in 44% of the patients in Group 2 and could not retrieve due to retrospective nature of the study.

CONCLUSION

This is the first study of its kind in head and neck cancer comparing complications in NACT patients undergoing surgery versus upfront surgery. It appears that postoperative major or minor complication rate does not increase following chemotherapy in head and neck cancer. There is a concern of increase blood loss following surgery which needs to be confirmed in further study.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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ANNUAL ISMPO MEETING 2015, 5-8 NOVEMBER, 2015: ORATIONS AND AWARDS

1. ISMPO Oration 1: Dr. Shripad Banavali, Tata Memorial Centre, Mumbai. Title of oration: Genomics, Proteomics and Metronomics

2. ISMPO Oration 2: Dr. Hemant Malhotra, SMS Medical College, Jaipur. Title of oration: CML in India: Problems and Perspectives

3. Principal Amritlal Mohanlal Pairkh Grant Award for joint 1st Abstract (cheque for Rs 25,000 + ESMO Traveling Fellowship to ESMO Asia Meeting in Singapore on 18-21 December 2015)– Dr. Nirav Thacker, Mumbai, Imatinib pharmacokinetics, its good efficacy but alarming toxicity in children with Chronic Myeloid Leukemia: A large observational study

4. Dr. Kalla Venkta Award for Joint 1st Abstract (cheque for Rs 30,000 + ESMO Traveling Fellowship to ESMO Asia Meeting in Singapore in December 2015) – Dr. Aditi Thanky, Bangalore. Predictive And Prognostic Implications of Variant Translocations In Indian Patients With Chronic Myeloid Leukemia.

5. CK Handoo Award for second best Abstract (cheque for Rs 20,000 + ESMO Traveling Fellowship to ESMO Asia Meeting in Singapore in December 2015) - Dr. Namratha, Udupa MS, Bangalore. Clinical Profile, Cytogenetics and Role of Immunophenotyping In Prognostication of Adult Acute Myeloid Leukemia In A Tertiary Care Centre.

6. CK Handoo Award for third best Abstract (cheque for Rs 15,000 + ESMO Traveling Fellowship to ESMO Asia Meeting in Singapore in December 2015) – Dr. Arun Chandrashekharan, Mumbai. Non-High Dose "Methotrexate (Hd-Mtx) Based, Dose-Dense (Dd) Chemotherapy(Ct) In Osteosarcoma: Is It Effective, Economic And Easy to Administer.

7. The following are 5 more abstracts that were found to be exceptionally good and the authors will be awarded ESMO Traveling Fellowship to ESMO Asia Meeting in Singapore in December 2015:

Kandula Ramu	Hyderabad	Concordance and discordance between fdg pet/ct and bone marrow biopsy in lymphoma patients: a single center retrospective study
Divya Bala Thumaty	Vellore	Adjuvant dox chemotherapy for operable gastric cancers
Anant Gokarn	Mumbai	Increased incidence of symptomatic hyponatremia with voriconazole prophylaxis during cyclophosphamide based conditioning in patients undergoing hematopoietic stem cell transplantation
Smitha C Saldanha	Bengaluru	Efficacy and safety of olanzapine versus aprepitant in highly emetogenic chemotherapy
Rakesh Pinninti	Mumbai	Metronomic chemotherapy in platinum insensitive failures and/ or early failures post multimodality management in oral cancers

8. ISMPO COPE Medal Winners for "The Best Outgoing Final Year DM/DNB Medical Oncology Student" in the exam conducted in January 2015 at Adyar Cancer Institute:

a. Dr Nagesh Sirsath, Gold Medal, Kidwai Institute, Bangalore

b. 2nd and 3rd: Dr Sandip Ganguly Kidwai Institute, Bangalore and Dr Mithun Chacko, RGCI, Delhi