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THE RELATIONSHIP BETWEEN CLINICAL STAGE AND THERAPEUTIC RESPONSE AFTER COMPLETE RADIOCHEMOTHERAPY IN NASOPHARYNGEAL CARCINOMA WHO TYPE III IN NGOERAH HOSPITAL DENPASAR

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ABSTRACT

Background: Nasopharyngeal cancer (NPC) is the fourth most common cancer in Indonesia, with WHO type III being the most aggressive yet highly responsive to radiochemotherapy. Various factors can impact treatment outcomes. **Objective:** To determine the relationship between clinical stage and therapeutic response after complete radiochemotherapy in patients with WHO type III NPC. **Methods:** This retrospective cohort study evaluated 148 WHO type III NPC patients who completed radiochemotherapy at Ngoerah Hospital (2020–2023). Patients were classified into early-stage (stage I-II, n=74) and advanced-stage (stage III-IVB, n=74) groups. Three months post-treatment, therapeutic response was assessed using RECIST 1.1 criteria (CR, PR, PD, SD) following re-staging procedures (imaging and diagnostics). A comparative analysis examined CR rates between the two groups and the relationship between clinical stage and treatment response. **Results:** The overall therapeutic response in this study was 27.7% CR, 22.3% PR, 25.0% SD, and 25.0% SD. Pre-radiochemotherapy clinical stage was significantly associated with the therapeutic response after complete radiochemotherapy. WHO type III NPC patients with advanced stage had a 37 times higher risk of non-CR than patients with early stage after adjustment for age, gender, and main symptoms (adjusted RR = 37.404; IK95% 8.308-168.393; p<0.001). **Conclusion:** Clinicians should prioritize early detection in high-risk patients with WHO type III NPC, as advanced-stage cases have poorer therapeutic responses. Patient education is crucial to ensure understanding of the disease progression and therapy prognosis, especially for advanced stages.

BACKGROUND

Nasopharyngeal carcinoma (NPC) is a malignancy in the head and neck region that originates from the squamous epithelium of the nasopharyngeal mucosa. NPC is one of the most common head and neck cancers worldwide, with an annual incidence of 133,354 new cases and 80,008 deaths globally in 2020. The incidence of NPC is known to be significantly influenced by geographical variation. While the incidence rate of NPC is less than 1 per 100,000 population in European and North American countries, it is notably higher in regions such as North Africa, East Asia, and Southeast Asia.[1,2]

In Indonesia, NPC ranks as the fourth most prevalent cancer after breast cancer, cervical cancer, and lung cancer. The incidence rate of NPC in Indonesia is reported at 5.56 per 100,000 population, equating to approximately 1,000 new cases per month. However, the actual incidence of NPC may be higher due to limited data on the overall incidence of NPC in the country. Denpasar City is one of the regions with a relatively high incidence rate, reaching 8.41 per 100,000 population.[3,4]

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The majority of NPC cases in Asia, including Indonesia, are histologically classified as undifferentiated non-keratinizing carcinoma, which falls under the World Health Organization (WHO) histopathological subtype III.[3,4] This WHO subtype III NPC is strongly associated with Epstein-Barr Virus (EBV) infection and has a higher propensity for distant organ metastasis. However, it also demonstrates better sensitivity to chemotherapy and radiotherapy.[5,6] While WHO subtype III NPC tends to respond favorably to therapy, therapeutic response to radiochemotherapy is also influenced by other factors, such as the clinical stage of the disease.

A study by Susanto et al. revealed a significant relationship between clinical staging and therapeutic response following complete radiochemotherapy in NPC patients ($p < 0.001$), where patients with more advanced clinical stages exhibited lower complete response (CR) rates.[7] Similarly, Li et al. reported a significant difference in clinical response rates after radiochemotherapy ($p = 0.001$) between NPC patients with clinical stages I-II and III-IV.[8] However, a study by Korkmaz et al. contradicted these findings, reporting no difference in clinical staging between NPC patients with CR and incomplete response (IR) following radiochemotherapy.[2] This indicates that the relationship between clinical staging and therapeutic response in NPC post-radiochemotherapy remains controversial.

To date, studies exploring the relationship between clinical staging and therapeutic response after radiochemotherapy in NPC patients are still limited. In Indonesia, only one study has analyzed the correlation between clinical characteristics and radiochemotherapy response in NPC patients. This evaluation of therapeutic response is crucial for assessing treatment success and planning further therapy. Therefore, this study aims to describe the therapeutic response following complete radiochemotherapy and its relationship with the clinical staging of WHO subtype III NPC at Ngoerah Hospital in Denpasar.

METHODS

This study is an observational analytic study with a retrospective cohort design aimed at evaluating the relationship between clinical stage and therapeutic response after complete radiochemotherapy in patients with WHO type III nasopharyngeal carcinoma (NPC). Data were obtained from medical records of patients at the ENT Clinic of Ngoerah Hospital, with the study conducted from September to December 2024. This study was conducted at the Outpatient Clinic and Inpatient Ward of the Otorhinolaryngology-Head and Neck Surgery Department, Ngoerah Hospital, Denpasar. The research was carried out over a three-month period, from April 1, 2024, to July 30, 2024, utilizing an observational analytic design with a cross-sectional methodology. Ethical approval for this study was obtained from the Research and Development Unit of the Faculty of Medicine, Udayana University, as stated in Ethics Statement Letter No. 2331/UN14.2.2.VII.14/LT/2024.

The target population comprises adult patients (≥18 years) diagnosed with WHO type III NPC who have completed radiochemotherapy between January 2020 and December 2023. The study sample was selected using consecutive sampling until a minimum of 148 patients was reached. The sample represents a subset of the target population, specifically adult patients with WHO type III NPC who underwent therapy at Ngoerah Hospital during the specified period, meeting the inclusion criteria and not falling under the exclusion criteria.

The inclusion criteria for this study are adult patients aged ≥18 years diagnosed with WHO type III NPC based on histopathological examination of tumor tissue biopsy, patients who received radiotherapy and neoadjuvant chemotherapy at Ngoerah Hospital with a regimen consisting of six cycles of neoadjuvant chemotherapy using brexel and carboplatin, followed by intensity-modulated radiotherapy (IMRT) at a dose of 60-70 Gy per day for 33-35 cycles. Additionally, patients must have undergone contrast-enhanced head CT scans, chest X-rays, liver ultrasound, and bone surveys at the hospital before starting therapy and three months after completing the radiochemotherapy regimen, with complete medical record data available.

The exclusion criteria include patients with a history of prior surgical therapy, specifically nasopharyngectomy performed before completing the radiochemotherapy regimen or before the re-staging assessment post-completion of radiochemotherapy.

Data analysis was conducted using SPSS version 26.0 and included descriptive analysis to characterize

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the subjects, proportional comparison analysis to evaluate therapy response based on clinical stage, and logistic regression to assess the relationship between clinical stage and therapeutic response, accounting for potential confounding variables.

RESULTS

This study involved 148 patients with WHO type III nasopharyngeal carcinoma (NPC) who had completed radiochemotherapy at Ngoerah Hospital, Denpasar. The mean age of patients in the study was 54.26 ± 10.90 years. The majority of patients were male (68.2%) and aged 41-60 years (61.5%).

The clinical manifestations reported by WHO type III NPC patients in this study were diverse, including neck lumps, nasal obstruction, epistaxis, chronic rhinorrhea, dysphagia, blood-stained discharge, vision disturbances, tinnitus, and headaches. The most frequently reported primary symptoms were neck lumps (33.1%), epistaxis (21.6%), and headaches (20.9%).

In terms of clinical staging, nearly half of the WHO type III NPC patients were in stage II (47.0%). Among the 23 patients with stage IVB NPC, distant metastases were identified, with bones being the most common site (91.0%), followed by the lungs (8.7%). Evaluation three months after completing radiochemotherapy showed that 27.7% of patients achieved a complete response (CR), 22.3% achieved a partial response (PR), 25.0% exhibited stable disease (SD), and 25.0% had progressive disease (PD). Detailed characteristics of WHO type III NPC patients are presented in Table 1.

Table 1. Characteristics of WHO type III NPC patients

Characteristics	Total (n=148)
Age (years), mean ± SD	54,26 ± 10,90 years old
Age group, n (%)	
18-25	1 (0.7)
26-40	16 (10.8)
41-60	91 (61.5)
>60	40 (27.0)
Sex, n (%)	
Male	101 (68.2)
Female	47 (31.8)
Main symptoms, n (%)	
Neck lumps	49 (33.1)
Nasal obstruction	12 (8.1)
Epistaxis	32 (21.6)
Chronic rhinorrhea	1 (0.7)
Dysphagia	1 (0.7)
Bloody stained discharge	2 (1.4)
Visual disturbances	7 (4.7)
Tinnitus	13 (8.8)
Headache	31 (20.9)
Clinical stage, n (%)	
Stage I	4 (2.7)
Stage II	70 (47.3)
Stage III	24 (16.2)
Stage IVA	27 (18.2)
Stage IVB	23 (15.5)
Therapeutic response, n (%)	
Complete response (CR)	41 (27.7)
Partial response (PR)	33 (22.3)
Stable disease (SD)	37 (25.0)
Progressive disease (PD)	37 (25.0)

To determine the influence of patient characteristics on the therapeutic response after completing radiochemotherapy in WHO type III NPC patients, the therapeutic response was reclassified into CR and non-CR. The statistical analysis comparing the proportions of therapeutic responses across different characteristics is presented in Table 2.

Based on the age groups of patients, the majority of non-CR patients were found in the 41–60 years age group (62.6%). However, when comparing the proportions of CR and non-CR responses, no significant differences were observed in the distribution of therapeutic responses across all age groups (p = 0.746). This indicates that age does not have a significant relationship with therapeutic response following complete chemoradiotherapy in WHO Type III NPC patients in this study.

Table 2. The relationship between age, gender, and main symptoms with therapeutic response after complete radiochemotherapy in WHO type III NPC patients

Characteristics	Therapy response, n (%)		P value
	Non-CR (n = 107)	CR (n = 41)	
Age (years)			0.746
18-25	1 (0.9)	0 (0)	
26-40	10 (9.3)	6 (14.6)	
41-60	67 (62.6)	24 (58.5)	
>60	29 (27.1)	11 (26.8)	
Sex			0.425
Male	71 (66.4)	30 (73.2)	
Female	36 (33.6)	11 (26.8)	
Main symptoms			0.001*
Neck lumps	42 (39.3)	7 (17.1)	
Nasal obstruction	8 (7.5)	4 (9.8)	
Epistaxis	27 (25.2)	5 (12.2)	
Chronic rhinorrhea	1 (0.9)	0 (0)	
Dysphagia	1 (0.9)	0 (0)	
Bloody stained discharge	2 (1.9)	0 (0)	
Visual disturbances	6 (5.6)	1 (2.4)	

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Tinnitus	7 (6.5)	6 (14.6)
Headache	13 (12.1)	18 (43.9)

Similarly, there were no significant differences in the proportions of CR and non-CR responses between male and female patients (p = 0.425).

Conversely, a significant difference was observed in the proportions of CR and non-CR responses among different main symptom groups (p < 0.001). Patients most frequently achieving CR presented with the primary symptom of headache (43.9%), whereas non-CR therapeutic responses were predominantly found in patients with complaints of neck lumps (39.3%) and epistaxis (25.2%).

A comparative analysis of the proportion of CR and non-CR responses was conducted between patients with early-stage NPC (stage I-II) and advanced-stage NPC (stage III-IVB). The majority of patients achieving CR were those with early-stage NPC (95.1%), with only 2 patients with advanced-stage NPC achieving CR (Table 3). The results of the analysis demonstrated a significant relationship between clinical stage and therapeutic response following complete radiochemotherapy in WHO type III NPC patients (p < 0.001). The risk of non-CR following complete radiochemotherapy in WHO type III NPC patients with advanced-stage disease (III-IVB) was found to be 40 times higher than in patients with early-stage disease (I-II) (crude RR 40.11; 95% CI 9.156-175.740; p < 0.001).

Table 3. The relationship between clinical stage and therapeutic response after complete radiochemotherapy in patients with WHO type III NPC

Clinical Stage	Therapy response, n (%)		Crude RR	CI95%	P Value
	Non-CR (n = 107)	CR (n = 41)			
Advanced stage (Stage III-IVB)	72 (67.3)	2 (4.9)	40.114	9.156 - 175.740	<0.001
Early stage (Stage I-II)	35 (32.7)	39 (95.1)			

To confirm the relationship between clinical staging and therapeutic response post-complete chemoradiotherapy, a multivariate analysis was conducted to control for confounding factors. The results of the multivariate analysis are presented in Table 4. The analysis revealed that clinical staging remains a significant factor influencing therapeutic response post-complete chemoradiotherapy in WHO Type III NPC (nasopharyngeal carcinoma) patients, even after adjusting for age, sex, and primary symptoms. Advanced clinical stages (Stage III-IVB) were shown to increase the risk of non-CR (non-complete response) post-complete chemoradiotherapy by as much as 37 times in WHO Type III NPC patients (adjusted RR = 37.404; 95% CI: 8.308–168.393; p < 0.001). Conversely, after multivariate analysis, primary symptoms were no longer found to be significantly associated with therapeutic response post-complete chemoradiotherapy in WHO Type III NPC patients (p = 0.464). Similarly, age and sex remained non-significant factors in influencing therapeutic response post-complete chemoradiotherapy in WHO Type III NPC patients (p > 0.05).

Table 4. Results of multivariate analysis of factors affecting therapeutic response after complete radiochemotherapy in patients with WHO type III NPC

Factors	Detection system		
	Adjusted RR	CI95%	P Value
Age group (41-60 years)	9.60	0.393-2.348	0.929
Sex (Men)	0.547	0.206-1.451	0.266
Main symptoms (Neck lumps)	1.532	0.488-4.807	0.464
Clinical stage (Advanced stage)	37.404	8.308-168.393	<0.001

DISCUSSION

It is well established that NPC patients achieving CR after radiotherapy or radiochemotherapy have better survival rates, whereas those with non-CR responses exhibit lower 5-year OS.[2,9] This is attributed to the greater disease burden in non-CR patients due to residual cancer mass post-therapy. Consequently, identifying factors influencing therapeutic response in NPC patients is crucial.

In this study, patient age was not significantly associated with therapeutic response following complete radiochemotherapy (p = 0.746). This finding aligns with previous research. Peng et al., involving 231 NPC patients in China, demonstrated no significant difference in median age among

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patients with CR, PR, and SD responses (42 vs. 42 vs. 40 years; p = 0.492).[9] Similarly, Korkmaz et al. reported no significant difference in mean age between patients with IR and CR (45.19±14.5 vs. 48.3±11.9 years; p = 0.38).[2] Susanto et al. also found no significant difference in mean age among patients with CR, PR, SD, and PD responses (49.15±13.46 vs. 47.64±12.78 vs. 48.25±10.66 vs. 45.27±15.36 years; p = 0.744).[7] Li et al. showed that the CR rate at 3-4 months post-radiochemotherapy did not differ between patients aged ≤45 and >45 years (83.1% vs. 83.6%; p = 0.883).[8]

Several studies examining NPC prognosis have shown that older patients (over 60 years) have worse OS and progression-free survival (PFS).[10,11] However, therapeutic response rates do not differ significantly between younger and older patients. The poorer survival in older patients is likely due to higher comorbidity rates. Leu et al. demonstrated that while CR rates were similar between patients aged <40 and >65 years, older patients had higher comorbidity rates and lower survival. They hypothesized that metabolic or cardiovascular comorbidities were primary contributors to mortality in older NPC patients.[10] Similarly, Xiao et al. suggested that IMRT remained effective for older NPC patients, but non-tumor-related mortality was more common in this group. Older patients' inability to complete therapy regimens due to adverse effects or comorbidities may also contribute to poorer survival.[12] As this study only included NPC patients who completed radiochemotherapy, it highlights that complete therapy regimens, with appropriate dosing, can be effective even in older patients.

In this study, gender was not significantly associated with therapeutic response post-radiochemotherapy in WHO type III NPC patients (p > 0.05). This is consistent with previous research at Hasan Sadikin Hospital in Bandung involving 380 NPC patients, where CR, PR, SD, and PD responses were evenly distributed between male and female patients (p = 0.820).[13] Korkmaz et al. similarly found no statistical difference in IR and CR proportions between genders.[2] Peng et al., in a multi-center study involving 231 NPC patients in China, concluded that gender does not influence therapeutic response (p = 0.773).[9] Li et al. reported no significant difference in CR rates between male and female NPC patients at 3-4 months (83.1% vs. 83.7%; p = 0.880) and 6-9 months (91.4% vs. 91.2%; p = 0.916) post-radiochemotherapy. These findings confirm that gender does not affect therapeutic response in NPC patients.[8]

Male gender has been associated with poorer survival compared to females. However, research indicates that this is not due to differences in therapeutic response. Several theories suggest that better survival in females may be linked to lifestyle and health-seeking behaviors, with females tending to seek medical attention earlier, leading to earlier diagnosis and treatment. Additionally, hormonal factors might play a role, as improved survival in females has been observed primarily during premenopause and perimenopause, but not postmenopause. Hormones such as estrogen and progesterone are thought to slow tumorigenesis, resulting in more advanced clinical stages being observed predominantly in males. Therefore, the lower survival in males is likely influenced by tumor aggressiveness and clinical stage rather than therapeutic response.[14,15]

There were differences in CR and non-CR proportions among patients with different primary symptoms, with non-CR being more frequent in patients presenting with neck lumps. However, after multivariate analysis and adjustment for age, gender, and clinical stage, primary symptoms were no longer significantly associated with therapeutic response. While no studies have directly investigated the relationship between primary symptoms and therapeutic response, one study explored the relationship between primary symptoms and survival in NPC patients. Siti-Azrin et al. reported that neck lumps were the most common symptom in NPC patients (73.1%), but cranial nerve palsy symptoms, such as ophthalmoplegia, vision disturbances, and sensory deficits, were more closely associated with mortality (p = 0.012).[16] Cranial nerve palsy may indicate extensive tumor invasion, which correlates with poorer prognosis.[17] Neck lumps, being painless, are often overlooked, and their presence is associated with nodal metastasis.[6] This suggests that the relationship between primary symptoms and prognosis is primarily driven by tumor extension. This study also found that after adjusting for clinical stage, primary symptoms were no longer significantly associated with therapeutic response in WHO type III NPC patients following radiochemotherapy.

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Clinical stage has long been recognized as one of the prognostic factors in NPC. Studies have shown that NPC patients with early-stage disease (Stages I-II) have a better 5-year OS compared to those with advanced stages (Stages III-IVB). The relationship between therapeutic response rates and survival in NPC patients has also been demonstrated in previous studies, wherein CR is associated with better survival than non-CR.[8,9] However, research on the correlation between clinical stage and therapeutic response rates in NPC patients remains limited, with contradictory findings across studies. Establishing a significant relationship between clinical stage and therapeutic response in NPC could help explain why better survival is observed in early-stage patients and vice versa.

This study demonstrates that clinical stage is significantly associated with therapeutic response following radiochemotherapy in WHO type III NPC patients. This association remained significant even after adjustments for age, gender, and primary symptoms. Advanced clinical stages (Stages III-IVB) were found to significantly increase the risk of non-CR after completing radiochemotherapy by 37-fold (adjusted RR = 37.404; 95% CI 8.308–168.393; $p < 0.001$) in WHO type III NPC patients.

Susanto et al. also reported a significant association between clinical stage and therapeutic response based on RECIST 1.1 criteria in NPC patients ($p < 0.001$). PD was observed only in NPC patients with Stages IVA and IVB, while seven out of eight patients with SD were those with advanced stages (Stages IVA-IVB). However, this study did not evaluate or adjust for tumor histology or the type of therapy administered (radiotherapy alone or radiochemotherapy).[18] Li et al. also demonstrated that advanced-stage NPC (Stages III-IVB) had significantly lower CR rates than early-stage NPC (Stages I-II) both at 3-4 months post-radiochemotherapy (79.4% vs. 94.4%; $p < 0.001$) and at 6-9 months post-radiochemotherapy (89.1% vs. 97.9%; $p < 0.001$).[8]

Contrary to our findings, Korkmaz et al. reported that clinical stage was not significantly associated with therapeutic response (IR vs. CR; $p = 0.74$). However, the presence of metastasis was significantly associated with CR ($p = 0.014$). It is worth noting that the proportion of patients with early and advanced stages in the Korkmaz et al. study was unbalanced. Although all patients received the same regimen (radiochemotherapy), there were fewer early-stage patients compared to advanced-stage patients (22 vs. 70 patients). Furthermore, the study did not adjust for NPC histological type, which is a critical determinant of tumor cell sensitivity to radiotherapy.[2] Similarly, Peng et al. found no significant association between clinical stage and therapeutic response ($p = 0.948$). However, their study only compared patients with Stages III and IV, which might have masked significant differences in response rates between stages.[9]

WHO type III NPC is highly progressive yet radiosensitive and chemosensitive. Nevertheless, this study demonstrates differences in therapeutic response in WHO type III NPC patients based on clinical stage prior to treatment. Early-stage NPC responds better to therapy due to smaller initial tumor size, limited progression, and minimal invasion. Additionally, tumor cells in early-stage NPC are typically more homogeneous, leading to consistent sensitivity and response to radiochemotherapy. This may explain the better therapeutic response observed in early-stage NPC. Conversely, advanced-stage NPC, particularly with distant organ metastasis, is thought to exhibit more aggressive intrinsic characteristics. Another theory suggests that advanced-stage NPC is associated with specific molecular mutations that render cancer cells resistant to chemotherapy, such as the expression of multidrug resistance-associated protein-1 (MRP1) and annexin I resistance gene (ANX-I), which have been linked to the prognosis of NPC and other solid tumors.[9,14] Unfortunately, molecular testing is not yet a routine recommendation in clinical practice for NPC management. Future research could explore the relationship between advanced-stage NPC and poorer therapeutic response to radiochemotherapy by integrating molecular analysis into clinical studies.

CONCLUSION

Overall, the therapeutic response following complete radiochemotherapy in patients with WHO type III nasopharyngeal carcinoma (NPC) at the ENT-Head and Neck Surgery Clinic, Ngoerah Hospital, was as follows: CR in 27.7% of patients, PR in 22.3%, SD in 25.0%, and PD in 25.0%.

Clinical stage was found to be significantly associated with therapeutic response after complete

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radiochemotherapy in patients with WHO type III NPC at the clinic. Advanced-stage NPC (stage III-IVB) significantly increased the risk of non-CR by up to 37 times (adjusted RR = 37.404; 95% CI 8.308–168.393; $p < 0.001$).

Age, gender, and primary symptoms were not significantly associated with therapeutic response following complete radiochemotherapy in patients with WHO type III NPC at the ENT-Head and Neck Surgery Clinic, Ngoerah Hospital ($p > 0.05$).

ETHICAL APPROVAL

This research received approval from the Research Ethics Committee of the Faculty of Medicine, Udayana University, and Ngoerah Hospital in Denpasar, with the approval code 2331/UN14.2.2.VII.14/LT/2024, granted on September 18 of 2024.

CONFLICTS OF INTEREST

The authors declare no conflict of interest.

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AUTHOR CONTRIBUTIONS

Conceptualization, IBGHK, IGAN, SWDS; methodology, IBGHK, IGAN, SWDS; software, IBGHK, MLR, ARA; validation, IBGHK, KADS, MLR; formal analysis, IBGHK, KADS, MLR; investigation, IBGHK, KADS, ARA; resources, IBGHK; data curation, IBGHK; original draft preparation, IBGHK; review and editing, KADS, MLR, ARA; supervision, IGAN, SWDS, KADS, MLR, ARA.

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