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Efficacy and Safety of Biosimilar Cetuximab (CETUXA) in Locoregionally Advanced or Recurrent Squamous Cell Carcinoma of the Head and Neck: A Retrospective Multicenter Analysis..

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Introduction

Squamous cell carcinoma of the head and neck (SCCHN) cases account for about 5% of all newly diagnosed cancer cases, resulting in more than 300000 deaths per year.[1] Despite appropriate primary treatments, in approximately 50% to 60% of patients with stage III to IV disease, locoregional relapse occurs.[2]

A large proportion of patients presenting with stage I and II squamous cell carcinoma of the head and neck (SCCHN) will remain disease-free after single modality treatment. But the majority of patients present with a more advanced disease stage. Locoregionally advanced, recurrent, and metastatic SCCHN are a challenge to treat.[3]This subset of patient is not suitable for surgery or radiotherapy. Hence, systemic treatments and best supportive care are the preferred therapeutic options.

Till the early 2000s, patients with metastatic SCCHN had a median overall survival (OS) of only 6 months [4,5,6]Intensive research was conducted to develop new drugs to help improve survival in patients with metastatic SCCHN. One of the key drugs developed was the targeted therapy cetuximab [directed at the epidermal growth factor receptor (EGFR)]. Cetuximab has shown substantial efficacy for recurrent or metastatic (R/M) SCCHN treatment in combination with 5-fluorouracil and platinum-based chemotherapy (the EXTREME regimen).[4]In the EXTREME trial, the addition of cetuximab to platinum/5-fluorouracil as first-line treatment of recurrent/metastatic squamous cell carcinoma of the head and neck not only led to significant improvements in survival, response rate, and disease control, but also induced better symptom control in comparison with that observed with platinum/5-fluorouracil alone.[7]Subsequently, over the past decade, the EXTREME regimen continued to be considered as a first-line treatment option in selected cases, such as tumors with low PD-L1 expression or when immunotherapy is contraindicated, or for patients with disease progression after first-line immune checkpoint inhibitors are given as monotherapy. [8]

Taxanes have been commonly used to treat solid tumors, and they also have proven efficacy in SCCHN.[9,10,11]TPExtreme was the first large, phase 3, randomized trial comparing the TPEx regimen (cetuximab, taxane, and platinum) with the

EXTREME scheme as a first-line regimen[8]. This trial proved comparable efficacy outcomes in 539 R/M SCCHN patients with a median OS of 14.5 and 13.4 months using the TPEx and EXTREME regimens, respectively. The TPEx-treated patients had a more favorable toxicity profile, which resulted in improved patient compliance with the planned treatment (72% *vs* 44%) and fewer dose interruptions (10% *vs* 27%).[8]

But one limiting factor associated with the use of cetuximab is the cost burden, particularly in resource-constrained healthcare systems. In response to this challenge, biosimilar formulations of cetuximab have emerged as promising alternatives. Biosimilars, by definition, are highly similar to their reference biologic products in terms of quality, efficacy, and safety. The advent of biosimilar cetuximab presents a unique opportunity to mitigate healthcare costs while ensuring equitable access to patients battling SCCHN. Moreover, the comparable efficacy and safety of biosimilar cetuximab have fostered confidence and acceptance of biosimilar cetuximab in routine clinical practice.

Hence, it is imperative to assess the real-world effectiveness of the biosimilar cetuximab in the management of locoregionally advanced or recurrent SCCHN used in both the TPEx regimen and the EXTREME regimen in Indian patients.

1. METHODOLOGY

This retrospective study was conducted across multiple centers in India to assess the efficacy and safety of biosimilar cetuximab (CETUXA®, Alkem Laboratories Ltd, Mumbai) in patients with locoregionally advanced or recurrent squamous cell carcinoma of the head and neck (SCCHN). The study focused on evaluating the **objective response rate (ORR)** and identifying clinical factors associated with treatment response and prognosis in patients who received biosimilar cetuximab, either as monotherapy or in combination with investigator-selected chemotherapy or radiotherapy. Patients included in the study had a histologically confirmed diagnosis of squamous cell carcinoma of the head and neck or locoregionally advanced or recurrent disease. The patients had been treated with biosimilar cetuximab either alone or in combination with investigator-choice chemotherapy/radiotherapy. Availability of complete medical records, including baseline demographic data, treatment details, and follow-up information, was essential for the patient to be included in the study. Patients with non-squamous cell carcinoma histology or who had not been treated with the biosimilar cetuximab were excluded from the study.

The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. Independent ethics committee approval was obtained prior to data collection. Patient confidentiality was maintained throughout the study, and data were anonymized to protect patient privacy.

Patients included in the study had been treated with biosimilar cetuximab either alone or in combination with investigator choice chemotherapy/radiotherapy, patients whose complete medical records including baseline demographic data, treatment details, and follow-up information were available.

Data from these patients were retrospectively extracted from electronic medical records, pathology reports, and imaging studies, and was duly analyzed to provide a comprehensive overview of patient demographics, tumor characteristics, treatment regimens, and clinical outcomes. Parameters assessed included demographics(age, gender), tumor characteristics (site, stage, histological subtype), Treatment regimens, including the specific use of biosimilar cetuximab in isolation or in conjunction with investigator-selected chemotherapy or radiotherapy. Treatment response was evaluated, incorporating radiological assessments to gauge tumor size reduction or disease stabilization. Additionally, adverse events associated with treatment were systematically documented to assess safety profiles and inform clinical decision-making. Subsequently, all gathered information was securely entered into an electronic database, safeguarding patient privacy and enabling robust analysis to derive meaningful conclusions regarding the real-world effectiveness of biosimilar cetuximab in the management of SCCHN.

Response to treatment was defined as complete response, partial response, stable disease, or progression using the RECIST 1.1 criteria. (Table)

Figure 1: Criteria for defining response to treatment[12]

Target lesions	Non-target lesions	New lesions	Overall response
CR	CR	No	CR
CR	Non-CR/non-PD	No	PR
CR	Not evaluated	No	PR
PR	Non-PD or not all evaluated	No	PR
SD	Non-PD or not all evaluated	No	SD
Not all evaluated	Non-PD	No	NE
PD	Any	Yes or No	PD
Any	PD	Yes or No	PD
Any	Any	Yes	PD

CR = complete response, PR = partial response, SD = stable disease, PD = progressive disease, and NE = inevaluable.

Statistical analysis

The association of different parameters, such as age, gender, and responses, was assessed using the chi-square test of association with the level of significance set at $p<0.05$.Analysis of variance (ANOVA) was used for the comparison of means among multiple groups. This study was a retrospective real world study. It included data of patients treated with Cetuximab in the real-world setting. Hence all analysis was descriptive.

2. RESULTS

A total of **505 patients** were enrolled in the study. The patients were treated by 5 investigators practicing at tertiary care center for cancer. The **mean age** was **55.7 ± 9.3 years**, with the highest prevalence of SCCHN observed in the **40–60 years** age group (**62.6%**). A **male predominance** was noted (**84.6%**) (Table 1a).Of the 505 patients evaluated, **175 (34.7%)** had **locoregionally advanced** disease, **167 (33.1%)** had **metastatic** disease, and **163 (32.3%)** presented with **recurrent locoregional** disease. Tumors from unspecified sites were grouped as "Others" (16.03%).

Table 1a: Demographics of patients enrolled in the study

Age(yrs)	**Number of patients (%)**
<40	27 (5.3)
40-60	316 (62.6)
>60	162(32.1)
Gender	
Male	427 (84.6)
Female	78 (15.4)
Total	505(100)

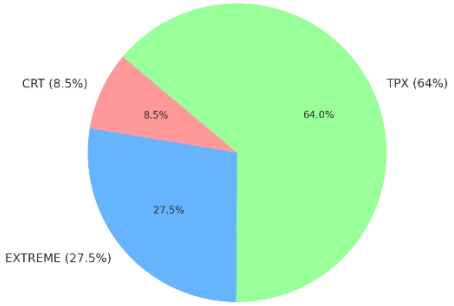
The most common primary sites of SCCHN were the **buccal mucosa (20.9%)**, **tongue (15.2%)**, and **oral cavity (6.5%) (Table 1b)**

Table 1b: Sites of tumor

Site of the tumor	No. of cases (%)
Buccal mucosa	106 (20.9)
Tongue	77 (15.2)
Oral cavity	33 (6.5)
Pharynx	21 (4.2)
Larynx	15 (3.0)
Tonsil	9 (1.8)
Lip	2 (0.4)
Maxilla	2 (0.4)
Nasal cavity	1 (0.2)
Others	95 (18.83)
Right Alveolus	1 (0.2)
Total	505 (100)

The TPEx regimen was prescribed in 64% of patients, while 27.5% of patients received the EXTREME regimen (Figure 1).

Figure 2: Treatment regimen used with cetuximab



TPEx = Docetaxel + Cisplatin + Cetuximab, EXTREME = Cetuximab + Platinum + 5-FU, CRT = Chemoradiotherapy with Cetuximab

Partial response (PR) was the most common outcome, observed in **78.2%** of patients. **Complete response (CR)** was seen in **8.3%**, **stable disease (SD)** in **8.5%**, and **disease progression (PD)** in **2.2%**. **Treatment discontinuation** occurred in **2.8%** of patients (Table 2).

Table 2: Distribution of Responses (bar chart)

Treatment response	Number of patients (%)
Partial Response(PR)	395(78.2)
Complete Response(CR)	42(8.3)
Disease Progression(PD)	11(2.2)
Stable Disease(SD)	43 (8.5)
Treatment Discontinuation	14 (2.8)

Patients on the **EXTREME regimen** had a higher **partial response rate** compared to those on the TPEx regimen (**82.0% vs. 77.4%; p<0.03**). However, more patients in the **TPEx group** had **stable disease** compared to the EXTREME group (**10.8% vs. 2.9%; p<0.03**). Complete response was highest with **CRT** (**11.6%**) compared to EXTREME (**8.6%**) and TPEx (**7.7%**) (Table 3).

Table3: Responses to treatment based on the Regimen/RT used with cetuximab

Responses	Regimen/RT used with cetuximab		
	CRT (N=43)	**EXTREME (N=139)**	**TPEx (N=323)**
Complete Response	5(11.6%)	12(8.6%)	25(7.7%)
Partial Response	31(72.1%)	114(82.0%)	250(77.4%)
Stable Disease	4(9.3%)	4(2.9%)	35(10.8%)
Disease progression	1(2.3%)	7(5.0%)	3(0.9%)
Treatment Discontinuation	2(4.7%)	2(1.4%)	10(3.1%)
Total	43(100%)	139(100%)	323(100%)

The overall response rate (ORR) was highest in the EXTREME group (90.6%), followed by the TPEx group (85.1%) and the CRT group (83.7%). The disease control rate (DCR) was highest in the TPEx group (96.0%), followed by EXTREME (93.5%) and CRT (93.0%). The overall ORR and DCR across all patients were 86.5% and 95.0%, respectively (Table 4).

Table 4: Overall Response Rate (ORR) and Disease Control Rate (DCR) by regimen

Parameter	Regimen/RT used with cetuximab			Overall
	CRT	**EXTREME**	**TPEx**	
Overall Response Rate (ORR)	36(83.7%)	126(90.6%)	275(85.1%)	437(78.2%)
Disease Control Rate (DCR)	40(93.0%)	130(93.5%)	310(96.0%)	480 (86.7%)
Total	43(100%)	139(100%)	323(100%)	505(100%)

Partial response was most common across all primary sites, particularly in **buccal mucosa (94/106)** and **tongue (66/77)**. Complete responses were more frequently observed in tumors of the **oral cavity**, **pharynx**, **lip**, and **right alveolus**.

Table 5: Comparison of responses to treatment based on site of SCCHN

SCCHN	Total	Complete Response (N=42)	Disease progression (N=11)	Partial Response (N=395)	Stable Disease (N=43)	Treatment Discontinue (N=14)
Buccal mucosa	106	0	0	94	12	0
Tongue	77	0	0	66	11	0
Oral cavity	33	7	1	21	3	1
Pharynx	21	4	0	14	3	0
Larynx	15	1	2	11	1	0
Tonsil	9	0	0	6	3	0
Lip	2	1	0	0	1	0

Maxilla	2	0	0	2	0	0
Nasal cavity	1	0	0	1	0	0
Right Alveolus	1	1	0	0	0	0
Others	95	14	1	90	1	0

Adverse events were reported in **31.9%** of patients (Table 6). The most frequently observed adverse event was **skin rash**, seen in **26.9%** overall, most commonly among TPEx-treated patients (**30.6%**) compared to EXTREME (**17.2%**) and CRT (**25.5%**)

Table6: Comparison of adverse effects with different treatment regimens

Adverse effects	**Regimen/RT used with cetuximab**			**Total N=505**
	CRT N=43	**EXTREME N=139**	**TPEx N=323**	
Total	14 (32.5%)	32 (23.02%)	115 (35.6%)	161 (31.9%)
Skin Rash	11 (25.5%)	24 (17.2%)	99 (30.6%)	136 (26.9%)
Acneform Rash Grade 1	2 (4.65%)	5 (3.5%)	3 (0.92%)	10 (1.98%)
Diarrhoea	1 (2.3%)	1 (0.71%)	2 (0.61%)	4 (0.79%)
Headache	0	0	2 (0.61%)	2 (0.39%)
Mucositis	0	0	2 (0.61%)	2 (0.39%)
Fatigue	0	0	2 (0.61%)	2 (0.39%)
Constipation	0	0	2 (0.61%)	2 (0.39%)
Dry Skin	0	0	1 (0.30%)	1 (0.19%)
Stomatitis	0	0	1 (0.30%)	1 (0.19%)
Dyspnea	0	0	1 (0.30%)	1 (0.19%)

3. DISCUSSION

SCCHN is often diagnosed late, and about 50–70% of patients present with stage III, IVb SCCHN.[13] Hence, a large subset of patients may not be amenable for undergoing surgery or radiotherapy; Systemic treatment and best supportive care can be the therapeutic options in these patients.

Although cetuximab is a promising drug, developing countries such as India face accessibility issues due to limited access and high cost of the drug. More than 76,000 patients are eligible for using cetuximab for SCHNN management, but only 1,611 (just 2%) patients can afford this therapy. The introduction of high-quality biosimilar products at an affordable cost has resulted in an increased number of patients having access to cetuximab.[14] In the multicentric cohort study by Falco, the TPEx regimen was associated with skin rash in 33.3% of patients.[15]In the current retrospective study, skin rash was reported in 29.7% of patients with the TPEx regimen. This indicates the comparable tolerability profile of the biosimilar cetuximab-based TPEx regimen in Indian patients.

The current retrospective, multicentre analysis provides a real-world perspective on the use of biosimilar cetuximab in patients with locoregionally advanced or recurrent SCCHN in India. Across a diverse cohort of 505 patients, the overall response rate (ORR) was 86.5%, with partial responses observed in 78.2% of patients. These findings are consistent with the efficacy demonstrated in clinical trials of innovator cetuximab and support the clinical utility of biosimilar formulations in routine practice.

Among the regimens studied, patients receiving the EXTREME protocol had a slightly higher partial response rate compared to those receiving the TPEX regimen (82.0% vs 77.4%, $p < 0.03$). Conversely, stable disease was more frequently

seen with TPEX (10.8% vs 2.9%). Complete response rates were highest among patients treated with chemoradiotherapy (11.6%). These variations in response likely reflect differences in patient selection, prior treatments, and tumour burden, though a more detailed subgroup analysis was not feasible within the current dataset.

Real-world usage patterns are often influenced by multiple factors including tolerability, cost, and availability. The findings of this study suggest that biosimilar cetuximab delivers comparable disease control when used with both EXTREME and TPEX regimens. Previous Indian studies, such as the randomized trial, have shown non-inferiority of the biosimilar compared to the innovator product. Our results align with this data in terms of safety and response outcomes.[14]

In terms of safety, adverse events were reported in 31.9% of patients, with skin rash being the most common. Rash was more frequently reported among TPEX-treated patients, which may be related to cumulative toxicities from the combination of taxane and platinum agents. While these findings are broadly in line with expected safety profiles for EGFR inhibitors, the AE reporting rate was lower than typically observed in prospective studies. This is likely due to the retrospective nature of the study and underreporting in medical records.

This study highlights the importance of biosimilars in improving access to targeted therapies in oncology. Cetuximab has been a well-established option in SCCHN, but affordability remains a barrier in India. As per internal estimates, fewer than 2% of eligible Indian patients currently access innovator cetuximab due to cost. The availability of a lower-cost, DCGI-approved biosimilar offers a meaningful solution to this gap. Wider adoption of such products may help increase the proportion of patients receiving guideline-based systemic treatment, especially in the public sector and smaller hospitals.

There are some limitations to this analysis. First, the retrospective design limits the ability to track long-term outcomes such as progression-free or overall survival. Second, adverse event data were dependent on documentation in patient files, which may not fully reflect all toxicities experienced. Lastly, treatment regimens were chosen at the discretion of the treating physician, and no adjustment was made for baseline prognostic differences, which may have influenced outcomes.

Despite these limitations, this study provides one of the largest Indian real-world datasets evaluating biosimilar cetuximab in SCCHN. The results reaffirm its clinical effectiveness and tolerability in both TPEX and EXTREME regimens and support its continued use as a cost-effective option in oncology practice.

4. CONCLUSION

This retrospective real-world analysis suggests that biosimilar cetuximab demonstrates favorable tolerability and encouraging response rates when used in combination regimens for advanced or recurrent SCCHN in Indian settings. The non-inferiority of biosimilar cetuximab to the innovator as established in pivotal clinical trials offers a proven cost-effective treatment for SCCHN patients in the real-world setting.

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