The Oncologist®

Clinical Trial Results

Single Arm, Phase II Study of Cisplatin, Docetaxel, and Erlotinib in Patients with Recurrent and/or Metastatic Head and Neck Squamous Cell Carcinomas

William N. William Jr.,[a] Anne S. Tsao,[a] Lei Feng,[a] Lawrence E. Ginsberg,[a] J. Jack Lee,[a] Merrill S. Kies,[a] Bonnie S. Glisson,[a] Edward S. Kim[b]

[a]The University of Texas MD Anderson Cancer Center, Houston, Texas, USA; [b]Levine Cancer Institute, Charlotte, North Carolina, USA

Disclosures of potential conflicts of interest may be found at the end of this article.

Trial Information

- **ClinicalTrials.gov Identifier**: NCT00076310
- **Sponsor(s)**: Genentech, OSI Pharmaceuticals, and Sanofi Aventis
- **Principal Investigator**: William Nassib William Jr.
- **IRB Approved**: Yes

Lessons Learned

- The combination of cisplatin, docetaxel, and erlotinib as frontline treatment for recurrent and/or metastatic head and neck squamous cell carcinomas led to a response rate of 62%.
- This result exceeded the prespecified target response rate of 50% and represented an improvement compared with historical controls.
- This regimen warrants further investigation.

Abstract

Background. The epidermal growth factor receptor (EGFR) plays a key role in the carcinogenesis of head and neck squamous cell carcinomas (HNSCC). We conducted this clinical study to test the hypothesis that the addition of erlotinib to first-line cisplatin and docetaxel for patients with recurrent and/or metastatic HNSCC would yield a response rate of at least 50%, representing an improvement from historical controls.

Methods. Patients with recurrent and/or metastatic HNSCC, with at least one measurable lesion, no prior chemotherapy for recurrent and/or metastatic disease, prior combined modality therapy completed >6 months before enrollment, and performance status $\leq$2 were treated with cisplatin, docetaxel, and erlotinib for up to six cycles, followed by maintenance erlotinib until disease progression. The primary endpoint was response rate.

Results. Fifty patients were enrolled (42 male, 12 never smokers, 19 with oropharynx cancer). The median number of cycles was five; 31 patients initiated maintenance erlotinib; 14 patients required erlotinib dose reductions. The objective response rate was 62%, and the median progression-free and overall survival were 6.1 and 11.0 months, respectively. Toxicity profiles were consistent with the known side effects of the study drugs.

Conclusion. The study met its primary endpoint and improved response rates compared with historical controls. The findings support further evaluation of the regimen for recurrent and/or metastatic HNSCCs. ***The Oncologist*** 2018;23:526–e49

Discussion

This single-arm, single-institution, phase II study was designed to test the hypothesis that the addition of erlotinib to first-line cisplatin and docetaxel for patients with recurrent and/or metastatic HNSCC would yield a response rate of at least 50%, representing an improvement over historical controls (the response rate to cisplatin and docetaxel alone observed in a previous trial led by the MD Anderson Cancer Center was 40%). The primary endpoint of the study was met, with an observed objective response rate of 62%. Moreover, the median progression-free survival (6.1 months) and overall survival (11.0 months) achieved by our patient cohort compared favorably with historical controls with chemotherapy alone.

These results are in accordance with a phase I/II clinical trial evaluating the combination of cisplatin and erlotinib in this setting, which showed a response rate of 21%, considered to be

Correspondence: William N. William Jr., M.D., The University of Texas MD Anderson Cancer Center, 1515 Holcombe Boulevard, Unit 432, Houston, Texas 77030, USA. Telephone: 713-792-6363; e-mail: williamwilliamjr@gmail.com Received November 7, 2017; accepted for publication December 12, 2017; published Online First on January 25, 2018. http://dx.doi.org/10.1634/theoncologist.2017-0661

higher than what would be expected with cisplatin alone. Our data add to the growing body of evidence showing that EGFR tyrosine kinase inhibitors have limited activity as monotherapy but may improve outcomes when combined with cytotoxic agents, especially when given in the frontline setting.

In addition to tyrosine kinase inhibitors, EGFR antibodies have also been investigated in phase III trials of recurrent and/or metastatic HNSCC. Currently the combination of platinum, 5-fluorouracil, and cetuximab is considered a standard first-line treatment, given improvements in response rates (20% vs. 36%), median progression-free survival (3.3 vs. 5.6 months), and overall survival (7.4 vs. 10.1 months), when compared with platinum plus 5-fluorouracil alone. The results of our clinical trial are comparable to those obtained with platinum, 5-fluorouracil, and cetuximab. One advantage of the regimen studied herein is the use of a drug that can be administered orally or via feeding tube, obviating the need for weekly infusions, especially in the maintenance setting for patients who achieve longer-term disease control. On the other hand, 40% of our patients experienced diarrhea (10%, grade 3 or 4), which probably resulted from additive toxicities of docetaxel and erlotinib and deserves attention and careful support.

The limited sample size of this trial (with only 19 patients with oropharynx cancer) precludes any conclusions about the efficacy of the regimen in disease that is positive versus negative for human papilloma virus, and this parameter has not been evaluated.

Outcome	Efficacy
Complete response, *n* (%)	4 (8)
Partial response, *n* (%)	27 (54)
Stable disease, *n* (%)	13 (26)
Partial disease, *n* (%)	3 (6)
Not evaluable	3 (6)
Overall response rate (CR + PR)	31 (62)
Disease control rate (CR + PR + SD)	44 (88)
Progression-free survival, months, median (95% CI)	6.11 (5.32–7.59)
Overall survival, months, median (95% CI)	11.0 (8.28–14.9)

In summary, the results presented herein provide support for further investigations of the regimen. Indeed, on the basis of these findings, we launched and completed a randomized, double-blind, placebo-controlled phase II study of platinum and docetaxel with or without erlotinib. Results recently presented in abstract form confirmed the superiority of the erlotinib-containing arm. Taken together, the data from the single-arm and randomized phase II trials provide strong rationale for the use of platinum, docetaxel, and erlotinib as frontline therapy for recurrent and/or metastatic HNSCCs.

Trial Information

Disease	Head and neck cancers
Stage of Disease/Treatment	Metastatic/advanced
Prior Therapy	None
Type of Study - 1	Phase II
Type of Study - 2	Single arm
Primary Endpoint	Overall response rate
Secondary Endpoint	Progression-free survival
Secondary Endpoint	Toxicity

Additional Details of Endpoints or Study Design

The overall response rate was the primary endpoint of the study and was determined using RECIST version 1.0. The response status was evaluated after two cycles of treatment and confirmed between 4 and 6 weeks thereafter. A Bayesian design based on predictive probabilities was employed to allow for early stopping if the accumulating evidence suggested treatment ineffectiveness. The maximum calculated sample size was 50 patients, and outcomes were evaluated after the first 15 and 30 patients were treated. If at either interim analysis the predictive probability of a positive study (i.e., posterior probability of response rate $>30\%$ at least 90%) was low ($<.05$), the trial would be stopped. The rule corresponded to stopping the trial if one saw three or fewer responders in 15 patients or 9 or fewer responders in 30 patients. This design provided 92% power with an α of 0.08 to detect a true response rate of 50%.

Eligible patients were required to have histologically or cytologically confirmed metastatic or recurrent head and neck squamous cell carcinoma, with at least one measurable lesion according to RECIST version 1.0; no prior chemotherapy for metastatic or recurrent disease; completed prior combined modality therapy for at least 6 months; Eastern Cooperative Oncology Group (ECOG) performance status <2; and normal organ and marrow function, including leukocytes $>3{,}000/\mu L$, absolute neutrophil count $>1{,}500/\mu L$, platelets $>100{,}000/\mu L$, hemoglobin $\geq$ 8 g/dL, total bilirubin within normal institutional limits, aspartate aminotransferase/alanine aminotransferase $<2.5 \times$ the institutional upper limit of normal (ULN) if alkaline phosphatase is $<$ULN (alkaline phosphatase may be up to $4 \times$ ULN if transaminases are $<$ULN), creatinine $<2.0 \times$ ULN or creatinine clearance >60 mL/min/1.73 m^2 for patients with creatinine level above institutional normal. Exclusion criteria included HNSCC of the nasopharynx; history of nonpalliative radiation for metastatic and/or recurrent disease; prior anti-EGFR biologic therapy; brain metastases; pre-existing grade 2 or greater peripheral neuropathy (by the National Cancer Institute Common Terminology Criteria version 2.0); or uncontrolled intercurrent illness.

Investigator's Analysis	Active and should be pursued further

Drug Information

Drug 1

Generic/Working Name	Cisplatin

Drug Type	Small molecule
Drug Class	Platinum compound
Dose	75 milligrams (mg) per square meter (m^2)
Route	IV
Schedule of Administration	On day 1 every 21 days for a maximum of six cycles
Drug 2	
Generic/Working Name	Docetaxel
Drug Type	Small molecule
Drug Class	Tubulin/microtubules targeting agent
Dose	60–75 milligrams (mg) per square meter (m^2)
Route	IV
Schedule of Administration On day 1 every 21 days for a maximum of six cycles. The first six patients received docetaxel 60 mg/m^2. Escalation of the docetaxel dose to 75 mg/m^2 was allowed for patients experiencing minimal toxicity (grade $\leq$2) after the first cycle. All subsequent patients were treated with docetaxel 75 mg/m^2.	
Drug 3	
Generic/Working Name	Erlotinib
Drug Type	Biological
Drug Class	EGFR
Dose	100–150 milligrams (mg) per flat dose
Route	Oral
Schedule of Administration Once daily, continuous dosing. The first six patients received erlotinib 100 mg/day. Escalation of the erlotinib dose to 150 mg/day was allowed for patients experiencing minimal toxicity (grade 2) after the first cycle. All subsequent patients were treated with erlotinib 150 mg/day.	

Patient Characteristics

Number of Patients, Male	**42**
Number of Patients, Female	**8**
Stage	Locoregional recurrence: 31 patients Metastatic disease: 19 patients
Age	Median (range): 57
Number of Prior Systemic Therapies	0
Performance Status: ECOG	0 — 7 1 — 41 2 — 2 3 — Unknown —

Additional details for Patient and Treatment Characteristics can be found in Tables 1 and 2.

Primary Assessment Method

Title	Total Patient Population
Number of Patients Screened	50
Number of Patients Enrolled	50
Number of Patients Evaluable for Toxicity	50
Number of Patients Evaluated for Efficacy	50
Evaluation Method	RECIST version 1.0
Response Assessment CR	$n = 4$ (8%)
Response Assessment PR	$n = 27$ (54%)
Response Assessment SD	$n = 13$ (26%)
Response Assessment PD	$n = 3$ (6%)
Response Assessment Other	$n = 3$ (6%)
(Median) Duration Assessments PFS	6.11 months, CI: 5.32–7.59
(Median) Duration Assessments OS	11.0 months, CI: 8.28–14.9
(Median) Duration Assessments Response Duration	4.89 months

Phase II Experimental Arm Adverse Events

	All Cycles						
Name	NC/NA	1	2	3	4	5	All Grades
Febrile neutropenia*	88%	0%	0%	12%	0%	0%	12%
Weight loss	76%	18%	6%	0%	0%	0%	24%
Vomiting	40%	34%	16%	8%	2%	0%	60%
Tinnitus	84%	16%	0%	0%	0%	0%	16%
Platelets	70%	24%	2%	2%	2%	0%	30%
Mucositis/stomatitis (clinical exam)	60%	32%	4%	4%	0%	0%	40%
Rash: acne/acneiform	16%	40%	38%	6%	0%	0%	84%
Neutrophils/granulocytes (ANC/AGC)	46%	6%	0%	12%	36%	0%	54%
Neuropathy: sensory	40%	56%	4%	0%	0%	0%	60%
Nausea	20%	52%	16%	12%	0%	0%	80%
Nail changes	74%	20%	6%	0%	0%	0%	26%
Infection with normal ANC or Grade 1 or 2 neutrophils	74%	12%	10%	4%	0%	0%	26%
Hypotension	80%	4%	4%	6%	6%	0%	20%
Sodium, serum-low (hyponatremia)	32%	44%	2%	18%	4%	0%	68%
Magnesium, serum-low (hypomagnesemia)	24%	56%	10%	10%	0%	0%	76%
Potassium, serum-low (hypokalemia)	66%	24%	2%	4%	4%	0%	34%
Calcium, serum-low (hypocalcemia)	58%	32%	6%	2%	2%	0%	42%
Potassium, serum-high (hyperkalemia)	80%	14%	6%	0%	0%	0%	20%
Calcium, serum-high (hypercalcemia)	90%	10%	0%	0%	0%	0%	10%
Hearing: patients without baseline audiogram and not enrolled in a monitoring program	84%	14%	2%	0%	0%	0%	16%
Fatigue (asthenia, lethargy, malaise)	14%	34%	46%	6%	0%	0%	86%
Edema: limb	50%	44%	2%	4%	0%	0%	50%
Taste alteration (dysgeusia)	86%	14%	0%	0%	0%	0%	14%
Dry skin	68%	26%	6%	0%	0%	0%	32%
Diarrhea	20%	34%	26%	14%	6%	0%	80%
Dehydration	72%	2%	6%	16%	4%	0%	28%
Creatinine	60%	30%	10%	0%	0%	0%	40%
Bilirubin (hyperbilirubinemia)	60%	28%	6%	4%	2%	0%	40%
Hemoglobin	22%	44%	20%	8%	6%	0%	78%
ALT, SGPT (serum glutamic pyruvic transaminase)	90%	10%	0%	0%	0%	0%	10%
Hair loss/alopecia (scalp or body)	40%	48%	12%	0%	0%	0%	60%
Alkaline phosphatase	72%	22%	4%	2%	0%	0%	28%

*Fever of unknown origin without clinically or microbiologically documented infection (ANC $<$1.0 x 10e9/L, fever $\geq$38.5 degrees C).
Abbreviations: AGC, agranulocytosis; ALT, alanine aminotransferase; ANC, absolute neutrophil count; NC/NA, no change from baseline/no adverse event; SGPT, serum glutamic pyruvic transaminase.

Assessment, Analysis, and Discussion

Completion	Study completed
Investigator's Assessment	Active and should be pursued further

This single-arm, single-institution, phase II study was designed to test the hypothesis that the addition of erlotinib to first-line cisplatin and docetaxel for patients with recurrent and/or metastatic head and neck squamous cell carcinoma (HNSCC) would yield a response rate of at least 50%, representing an improvement over historical controls (the response rate to cisplatin and docetaxel alone observed in a previous trial led by the MD Anderson Cancer Center was 40% [1]). The primary endpoint of the study was met, with an observed objective response rate of 62%. Moreover, the median progression-free (6.1 months) (Fig. 1) and overall (11.0 months) (Fig. 2) survival achieved by our patient cohort compared favorably with historical controls with chemotherapy alone [1].

This clinical trial was designed at a time when there was limited evidence of the activity of epidermal growth factor receptor (EGFR)-targeted agents in HNSCCs, especially in regard to tyrosine kinase inhibitors (TKIs) combined with chemotherapy. During the conduct and after completion of this study, evidence arose that EGFR TKIs as single agents had modest activity in HNSCC progressing after platinum-based therapy. Soulieres at al. demonstrated a response rate of 4.3% with single-agent erlotinib [2]. The response rate to single-agent gefitinib at a dose of 500 mg per day was 10.6% [3]. At a lower dose of 250 mg per day, it was 1.4% [4]. Gefitinib was subsequently compared with methotrexate in a phase III study and showed a response rate of 2.7% at 250 mg per day and 7.6% at 500 mg per day but failed to improve survival compared with the chemotherapy arm [5]. Afatinib elicited a response rate of 10% and improved progression-free survival (but not overall survival) over methotrexate in a phase III study [6]. Taken together, these data do not support the use of monotherapy with an EGFR TKI in pretreated HNSCC.

Strategies to improve the efficacy of these drugs included investigations of EGFR TKIs earlier in the course of the disease and/or combinations with cytotoxic agents. Our group [7] and others [8] demonstrated, for example, in separate studies in platinum-naïve, early stage, resectable HNSCC, that erlotinib was associated with response rates of 25%–29%, suggesting that the timing of EGFR TKI exposure may influence activity. Indeed, in the current clinical trial, erlotinib was given as first-line therapy for recurrent and/or metastatic disease, in patients with no recent exposure to platinum, and showed improved efficacy compared with historical controls. These results are in accordance with a phase I/II clinical trial evaluating the combination of cisplatin and erlotinib in this setting, which showed a response rate of 21%, considered to be higher than what would be expected with cisplatin alone, although the study did not meet the overly optimistic, prespecified target response rate improvement [9]. In contrast, a phase II study in previously treated patients with recurrent and/or metastatic HNSCC showed no benefits of adding gefitinib to docetaxel in regard to survival or response rates [10], again indicating that the use of EGFR TKIs in later lines of therapy may result in suboptimal outcomes.

In addition to TKIs, EGFR antibodies have also been investigated in phase III trials of recurrent and/or metastatic HNSCC [11–13]. Currently, the combination of platinum, 5-fluorouracil, and cetuximab is considered a standard first-line treatment, given improvements in response rates (20% vs. 36%), median progression-free survival (3.3 vs. 5.6 months) and overall survival (7.4 vs. 10.1 months), when compared with platinum plus 5-fluorouracil alone [12]. The results of our clinical trial are comparable to those obtained with platinum, 5-fluorouracil, and cetuximab. One advantage of the regimen studied herein is the use of a drug that can be administered orally or via feeding tube, obviating the need for weekly infusions, especially in the maintenance setting for patients who achieve longer-term disease control. On the other hand, 40% of our patients experienced diarrhea (10%, grade 3 or 4), which probably resulted from additive toxicities of docetaxel and erlotinib and deserves attention and careful support.

In an attempt to maximize benefit-risk ratios of EGFR inhibitors in HNSCCs, several groups have investigated candidate biomarkers of efficacy. Human papilloma virus (HPV) status was not found to be a predictive marker of benefit from cetuximab added to platinum and 5-fluorouracil in one phase III study [14]. In the randomized trial of platinum, 5-fluorouracil, and panitumumab, the addition of the EGFR antibody was associated with a trend toward improved outcomes primarily in the p16-negative subgroup [13] (although p16 scoring criteria in that study was different than what has been used in pivotal trials in locally advanced disease). Our study only included 19 patients with oropharynx cancers and we did not evaluate HPV/p16 status. However, given the small sample size and nonrandomized nature of this study, analysis of efficacy according to HPV status would likely be unable to provide meaningful conclusions. EGFR copy number gain failed as a predictive marker of benefit from cetuximab or gefitinib in the phase III studies [5, 15], indicating that the search for biomarkers in this setting is not straightforward and may require a comprehensive evaluation of multiple pathways, an effort that is currently underway using specimens collected during this study.

In summary, we demonstrated herein that the addition of erlotinib to first-line cisplatin and docetaxel led to improved response rates compared with historical controls. This clinical trial met its primary endpoint, providing support for further investigations of this regimen. Indeed, on the basis of these findings, we launched and completed a randomized, double-blind, placebo-controlled phase II study of platinum and docetaxel with or without erlotinib. Results recently presented in abstract form confirmed the superiority of the erlotinib-containing arm [16]. Taken together, the data from the described single-arm phase II trial and the randomized phase II trials provide a strong rationale for the use of platinum, docetaxel, and erlotinib as frontline therapy for recurrent and/or metastatic HNSCCs.

Acknowledgments

This work was supported by NIH grant P30 CA016672, Cancer Prevention Research Institute of Texas grant RP140464, and a grant from the Conquer Cancer Foundation.

Disclosures

William N. William Jr.: Roche/Genentech (C/A), Astellas Pharmaceuticals, Eli Lilly, Bristol-Meyers Squibb, Merck, Astellas Pharmaceuticals, Boehringer Ingelheim Pharmaceuticals (RF), AstraZeneca, Roche, Genentech (H); **Anne S. Tsao:** Boehringer-Ingelheim Pharmaceuticals, Bristol-Myers Squibb, EMD Serono, Genentech BioOncology, Eli Lilly, Merck, Novartis, Roche Laboratories, Takeda Oncology (C/A), Boehringer-Ingelheim Pharmaceuticals, Bristol-Meyers Squibb, Genentech, Eli Lilly, Merck (RF). The other authors indicated no financial relationships.

(C/A) Consulting/advisory relationship; (RF) Research funding; (E) Employment; (ET) Expert testimony; (H) Honoraria received; (OI) Ownership interests; (IP) Intellectual property rights/inventor/patent holder; (SAB) Scientific advisory board

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Figures and Tables

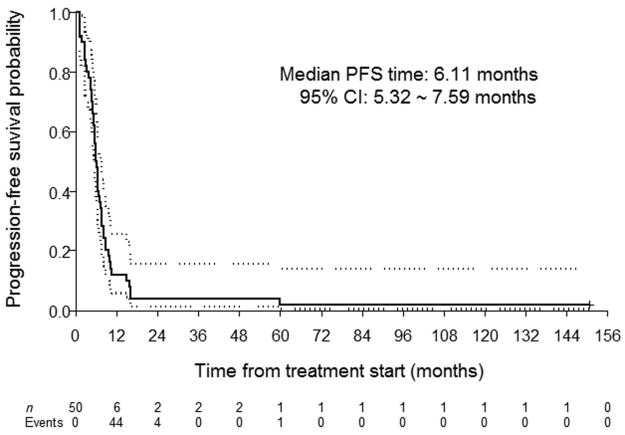

Figure 1. Progression-free survival (bold line) and 95% confidence interval (dotted lines).

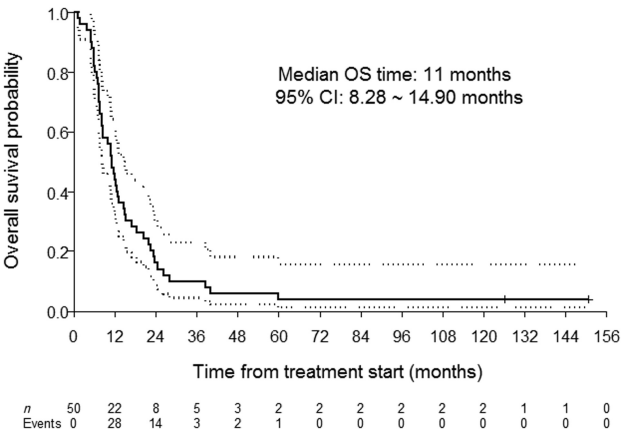

Figure 2. Overall survival (bold line) and 95% confidence interval (dotted lines).

Table 1. Patient characteristics

Characteristic	Number of patients, *n* (%)
Age, years, median (range)	57 (39–72)
Sex	
Male	42 (84)
Female	8 (16)
Performance status	
0	7 (14)
1	41 (82)
2	2 (4)
Disease status at entry	
Locoregional recurrence	31 (62)
Metastatic disease	19 (38)
Prior treatment	
Radiotherapy alone	4 (8)
Surgery + radiotherapy	20 (40)
Chemotherapy + radiotherapy	5 (10)
Chemotherapy + radiotherapy + surgery	14 (28)
Untreated	7 (14)
Smoking status	
Current	13 (26)
Former	25 (50)
Never	12 (24)
Primary site	
Oropharynx	19 (38)
Oral cavity	15 (30)
Larynx	11 (22)
Hypopharynx	3 (6)
Unknown primary site	2 (4)

Table 2. Treatment characteristics

Characteristic	Metric
Median number of cycles	
Cisplatin	5
Docetaxel	5
Erlotinib	5
Initiated maintenance erlotinib, *n*	
No	19
Yes	31
Median duration of maintenance erlotinib, weeks	17
Median dose intensity, mg/m^2	
Cisplatin	75
Docetaxel	75
Erlotinib dose reductions, *n*	
No	36
Yes	14