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Ototoxicity Monitoring: The Evolution of a Protocol for Head and Neck Cancer Patients

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Abstract

Objective. We evaluated an ototoxicity monitoring program (OMP) for improving audiologic follow-up in head and neck cancer (HNC) patients.

Study Design. Retrospective cohort study.

Setting. Tertiary academic center.

Methods. Two hundred and forty patients were recommended for chemotherapy between January 2017 and June 2022. An OMP was implemented in March 2021; every patient received an audiology referral and was contacted to schedule a pretreatment audiogram. Patients were divided into pre-OMP and post-OMP cohorts. Main outcome measures included rates of pretreatment audiograms, posttreatment audiograms, posttreatment otologic symptoms, and hearing aid utilization.

Results. There were 131 patients evaluated pre-OMP and 109 evaluated post-OMP. The mean age for all patients was 62.8 ± 11.9 years; 76.3% were male. After the implementation of the OMP, a significantly higher proportion of patients received a pretreatment audiogram (66.1% vs 34.4%, $P < .001$), with enrolled patients being 3.8 times more likely to obtain I (95% confidence interval: 2.2-6.6), $P < .001$). There was a significant increase in reported otologic symptoms after implementing the program (18% vs 36%, $P = .002$). However, the rate of hearing aid utilization decreased after OMP implementation (pre-OMP: 33% vs post-OMP: 13%, $P = .02$).

Conclusion. Implementation of an OMP significantly improved the proportion of HNC patients that underwent pretreatment audiograms prior to systemic therapy; however, audiologic follow-up remained largely unchanged in the posttreatment period.

Level of Evidence. Level 4.

Keywords

cisplatin, head and neck cancer, ototoxicity monitoring

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Chemotherapy and radiation are common tools for the treatment of head and neck cancer (HNC). More specifically, platinum-based chemotherapeutic drugs are widely used with the 3 most used agents being cisplatin, carboplatin, and oxaliplatin.[1,2] All 3 agents vary in their toxicity profiles, but cisplatin is a major cause of treatment-related hearing loss.[3-5] The ototoxic mechanism of cisplatin involves the generation of reactive oxygen species within the cochlea, which leads to oxidative stress and subsequent damage to both inner and outer hair cells. Furthermore, cisplatin induces inflammation and apoptosis in the cochlear hair cells. This cellular damage is often irreversible and dose-dependent, leading to progressive and permanent hearing loss.

Ototoxicity manifests as tinnitus, vestibular disturbances, or permanent hearing loss and is reported to occur in 40% to 80% of treated adult patients; globally this is estimated to be half a million cases per year.[4-6] Furthermore, the common use of concurrent radiation in HNC treatment places the adjacent cochlea at an even higher risk for treatment-related ototoxicity.[2] Cisplatin-based chemoradiation (CRT) has been shown to improve survival outcomes; however, the long-term ototoxic effects associated with therapy must be addressed as

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hearing loss may substantially impact survivorship in this patient population.

Currently, there are 2 national ototoxicity surveillance guidelines, and more than 10 grading systems proposed to better characterize cisplatin-induced ototoxicity.[2,7] The American Speech-Language-Hearing Association (ASHA) guidelines recommend a pretreatment audiogram, interval monitoring during treatment, and posttreatment monitoring immediately after, and 3 and 6 months after cisplatin therapy.[8] The American Academy of Audiology (AAA) guidelines also include a pretreatment audiogram, continuous monitoring during treatment, and posttreatment monitoring 3 months after treatment ends; the AAA further asserts that individuals undergoing concurrent radiation should receive annual monitoring for up to 2 years. The objectives behind both sets of guidelines include (1) early detection of hearing changes caused by cisplatin so that changes in treatment regimen can be considered, and (2) audiologic intervention can be implemented when a significant hearing impairment has developed.[9] Despite these recommendations, adherence to these guidelines remains a significant challenge.

Effective ototoxicity monitoring necessitates cohesive coordination between patients, oncologists, audiologists, and otolaryngologists, raising concerns about the practical challenges of balancing the patient burden of audiologic follow-up with oncologic surveillance.[5,10] A study by Santucci et al found poor adherence to national ototoxicity monitoring guidelines at a large academic medical center, with less than 25% of cisplatin-treated patients receiving a pretreatment audiogram.[11] The evaluation of audiologic follow-up patterns in HNC patients after the implementation of an established ototoxicity monitoring program (OMP) has only recently been investigated. A study on audiologic follow-up in OMP patients who had a pretreatment audiogram found a 75% follow-up rate for at least 1 posttreatment audiogram; however, follow-up rates dropped significantly after 6 months.[12]

While several studies have investigated general patterns in audiologic follow-up in HNC patients treated with cisplatin, there are few studies reporting on the implementation of an OMP; it remains unclear if a formal program significantly changes trends in audiologic care. This study aims to evaluate the effect of an OMP integrated into a comprehensive tumor board on audiologic follow-up in HNC patients. Findings from this study may help improve interventions aimed at reducing cisplatin-induced hearing loss. We hypothesized that the implementation of an OMP would increase adherence to ototoxicity monitoring guidelines.

Materials and Methods

We conducted a retrospective cohort study at a single tertiary academic center. We evaluated posttreatment audiologic follow-up in HNC patients before and after the implementation of an OMP. The Institutional Review Board of Thomas Jefferson University Hospital approved this study (Control #22E.298). Our study cohort included adults (age ≥18 years) with HNC who were recommended for chemotherapy ± radiation by our tumor board between January 2017 and June 2022. The OMP was implemented in March 2021 after which every patient recommended for chemotherapy automatically received an audiology referral and was contacted to schedule a pretreatment audiogram. Patients are then advised to schedule repeat audiology testing within 24 hours before each cisplatin cycle or within 72 hours for carboplatin to monitor for any auditory changes during treatment. Posttreatment testing is ideally completed within 6 months after treatment ends, with an initial retest approximately 1 week after treatment and a 12-week follow-up to align with positron emission tomography scans and head and neck oncology appointments. Any significant hearing changes, based on ASHA guidelines, are promptly reported to the referring physician or oncologist. If intervention is required, patients are quickly referred for a hearing aid evaluation with an audiologist. Additionally, patients who had their pretreatment audiogram at our institution underwent a high-frequency test protocol, while those who saw an outside audiologist were recommended for the same test. Patients with known bilateral profound sensorineural hearing loss seen on an audiogram prior to treatment and patients who received cancer treatment outside of Jefferson were excluded from the study.

The electronic medical record was used to record standard patient demographic, clinical, and oncologic data. Demographic variables included age at treatment initiation, gender, race, and insurance status. Race was categorized into white and non-white. Insurance status was dichotomized into private versus government-issued insurance. Clinical variables included completion of a pretreatment and/or posttreatment audiogram, posttreatment otologic symptoms, and hearing aid evaluation/utilization. Audiology clinic notes were used to report otologic symptoms and were categorized into all combinations of hearing loss, tinnitus, aural fullness, and middle ear effusion. Patient-reported hearing aid use was also determined based on the audiology/otology clinic notes. Hearing loss was defined as a pure-tone average of less than 25 at any tested frequency. Hearing aid utilization was defined as use at any point during treatment follow-up. Criteria for recommending a hearing aid included an audiogram demonstrating greater than 25 dB hearing loss and patient-reported communication difficulties. Patients with pretreatment hearing aid use were excluded from the hearing aid utilization analysis. Oncologic variables included the use of cisplatin in the CRT regimen, overall tumor stage, tumor location, and date of tumor board presentation.

Statistical Analysis

Standard descriptive statistics were used to characterize the patient cohort. Continuous variables were reported using mean and standard deviation or median and range. Differences between patients with and without audiologic follow-up after implementation of the OMP were evaluated

by unpaired t test, χ^2 test, or Fisher's exact test, as appropriate. Statistical analyses were conducted using IBM SPSS Version 28.0.1.0, and a $P < .05$ indicated statistical significance.

Binary logistic regression was conducted to identify factors associated with the success of obtaining a pretreatment audiogram and posttreatment audiogram. We evaluated potential confounders by first performing an univariable analysis; variables that had a P value less than .1 were excluded. Results were expressed as odds ratios (OR) with 95% confidence intervals (CIs).

Results

Demographics

The study included 240 patients with HNC who underwent chemotherapy at our center: 131 patients before the implementation of the OMP (pre-OMP cohort) and 109 after the implementation of the OMP (post-OMP cohort). In the total population, the mean age was 62.8 ± 11.9 years; 76.3% were male, 79.6% identified as white, 47.1% had private insurance, and 52.9% had Medicare insurance. Clinical characteristics revealed that 59.2% had a tumor stage greater than stage IV, 71.7% received cisplatin, and 93.8% underwent radiation. Demographic factors such as age ($P = .51$), gender ($P = .07$), race ($P = .94$), and insurance status ($P = .436$) showed no significant differences between the 2 groups (**Table 1**).

Table 1. Comparison of Patient Characteristics based on Ototoxicity Monitoring Program (OMP) Implementation

Characteristic (n = 366)	Pre-OMP, N = 131[a]	Post-OMP, N = 109[a]	P value[b]
Age, y (SD)	62.83 (10.37)	62.71 (11.48)	.85
Gender			.06
Male	106 (81%)	77 (71%)	
Female	25 (19%)	32 (29%)	
Race			.94
Non-white	27 (21%)	22 (20%)	
White	104 (79%)	87 (80%)	
Insurance			.39
Private	65 (50%)	48 (44%)	
Medicare	66 (50%)	61 (56%)	
Primary site location			.258
Hypopharynx	15 (11%)	6 (5.5%)	
Larynx	5 (3.8%)	10 (9.2%)	
Nasopharynx	9 (6.9%)	13 (12%)	
Oral cavity	26 (20%)	25 (23%)	
Oropharynx	59 (45%)	42 (39%)	
Other	14 (11%)	11 (10%)	
Unknown primary	3 (2.3%)	2 (1.8%)	
Tumor stage > IV	75 (57%)	67 (61%)	.508
Cisplatin	94 (72%)	78 (72%)	.973
Radiation	128 (98%)	97 (89%)	.005*
Pretreatment audiogram	45 (34%)	72 (66%)	<.001*
Posttreatment audiogram	25 (19%)	22 (20%)	.831

[a]Mean (SD); n (%).
[b]Wilcoxon rank sum test; Pearson's χ^2 test.
*P value is significant.

Trends Observed Before and After Implementation of the OMP

Among the 131 patients treated before the OMP and the 109 patients treated after, there were notable changes postimplementation. Significantly fewer patients in the post-OMP cohort underwent radiation compared to the pre-OMP cohort (97.7% vs 89.0%, respectively; $P = .007$). The implementation of the OMP led to a significant rise in the proportion of patients that underwent a pretreatment audiogram (pre-OMP: 34.4% vs post-OMP: 66.1%, $P < .001$). There was no significant difference in patients that underwent a posttreatment audiogram between cohorts (19.1% vs 20.2%, $P = .87$). Tumor stage, primary tumor site, and the proportion of patients receiving cisplatin-based chemotherapy did not differ significantly between cohorts ($P = .51$, $P = .26$, $P = .97$) (**Table 1**).

Factors Associated With Obtaining a Pretreatment Audiogram

Patients were compared based on whether they received an audiogram prior to treatment. Overall, patients placed on cisplatin-based chemotherapy regimens had a higher rate of obtaining a pretreatment audiogram (cisplatin: 77.8% vs no cisplatin: 22.2%, $P < .001$). The rate of obtaining a pretreatment audiogram increased notably after the implementation of the OMP (pre-OMP: 34.4% vs post-OMP: 66.1%, $P < .001$). No differences were observed in pretreatment audiogram acquisition across age, gender, race, insurance status, treatment location, tumor stage, or concurrent radiation treatment (**Table 2**).

Logistic regression analysis demonstrated that patients enrolled in the OMP were 3.8 times more likely to obtain a pretreatment audiogram (95% CI: 2.2-6.6, $P < .001$). The analysis also indicated a positive association between obtaining a pretreatment audiogram and receiving a posttreatment audiogram ($P < .001$). Other factors including gender, insurance, race, cisplatin treatment, and radiation treatment had no significant influence on the likelihood of obtaining a baseline audiogram (**Table 2**).

Factors Associated With Obtaining a Posttreatment Audiogram

Patients were compared based on whether they received a posttreatment audiogram after cancer treatment. The mean oncologic follow-up time for all patients was

Table 2. Logistic Regression Analysis of Factors Influencing Pretreatment Audiogram Completion

Characteristic	No pretreatment audiogram, N = 123[a]	Pretreatment audiogram, N = 117[b]	Univariate	Multivariate	
			P value[b]	OR (95% CI)	*P* value
Age, y (SD)	63.9 (10.5)	61.6 (11.2)	.63		
Gender			.76		
Male	95 (77%)	88 (75%)			
Female	28 (23%)	29 (25%)			
Race			.15		
Non-white	30 (24%)	19 (16%)			
White	93 (76%)	98 (84%)			
Insurance			.70		
Private	56 (46%)	57 (49%)			
Medicare	67 (55%)	60 (51%)			
OMP			<.001*	3.8 (2.2-6.6)	<.001*
No	86 (70%)	45 (39%)			
Yes	37 (30%)	72 (62%)			
Tumor stage > IV	75 (61%)	67 (57%)	.60		
Cisplatin use	81 (66%)	91 (78%)	.045	2.0 (1.1-3.6)	.03*
Radiation	116 (94%)	109 (94%)	.79		

Abbreviations: CI, confidence interval; OR, odds ratio.
[a]Mean (SD); n (%).
[b]Wilcoxon rank sum test; Pearson's χ^2 test.
*$P < .10$ included in the logistic regression model, $P < .05$ considered statistically significant.

30.7 ± 20.7 months. Among the patients, 28.3% (n = 68) were deceased, and 16.3% (n = 39) had less than 6 months of oncologic follow-up after the end of treatment. There was no difference in the likelihood of obtaining a posttreatment audiogram based on length of oncologic follow-up period. There was no notable difference in the percentage of patients who underwent a posttreatment audiogram between the pre-OMP and post-OMP cohorts (19.1% compared to 20.2%, $P = .87$). Overall, patients with a posttreatment audiogram were significantly more likely to have undergone a pretreatment audiogram (97.9% vs 2.1%, $P < .001$). Finally, patients receiving a cisplatin chemotherapy regimen had significantly higher odds of obtaining a posttreatment audiogram compared to those on all other chemotherapy regimens (OR = 1.9, $P = .03$, 95% CI: 1.0-3.6) (**Table 3**).

Posttreatment Otologic Symptoms

Out of 240 patients, 63 reported otologic symptoms following treatment. The most common symptom was hearing loss (n = 26, 10.8%), followed by isolated tinnitus (n = 14, 5.8%) and hearing loss with tinnitus (n = 11, 4.6%). There was a significant increase in reported otologic symptoms after implementing the OMP (pre-OMP: 18% vs post-OMP: 36%, $P = .002$).

Hearing Aid Utilization

In the total population, hearing loss was identified in 36% (n = 87) of patients, with 31.2% (n = 75) qualifying for a hearing aid; only 21 patients (28%) sought treatment with hearing aids. The rate of identifying hearing loss decreased after implementing the OMP (pre-OMP: 91% vs 73%, $P = .017$). Additionally, the rate of patients seeking hearing aids decreased postimplementation ($P = .019$) (**Table 4**).

Discussion

This retrospective cohort study investigated differences in audiologic follow-up patterns among HNC patients treated with chemotherapy ± radiation before and after the implementation of an OMP. We demonstrate that the implementation of an OMP led to a significant rise in the proportion of patients that underwent a pretreatment audiogram. Although no patient obtained more than 1 posttreatment audiogram, we found that patients with a pretreatment audiogram were significantly more likely to receive a posttreatment audiogram. Nonetheless, implementation of the OMP did not improve hearing aid utilization in patients with posttreatment hearing loss. Our findings indicate that implementing an OMP substantially increases the likelihood of HNC patients obtaining a pretreatment audiogram. Additionally, patients who had a pretreatment audiogram were more likely to pursue posttreatment evaluation at some point after completing therapy. This is the first study to assess the evolution of audiologic follow-up before and after the introduction of an OMP.

Obtaining an audiogram before initiation of cisplatin and between doses during treatment allows clinicians to

Table 3. Logistic Regression Analysis of Factors Influencing Posttreatment Audiogram Completion

Characteristic	No posttreatment audiogram, N = 193[a]	Posttreatment audiogram, N = 47[a]	Univariate	Multivariate	
			P value[b]	OR (95% CI)	*P* value
Age, y (SD)	63.3 (10.4)	60.6 (12.3)	.32		
Follow-up period, mo (SD)	29.8 (20.9)	34.8 (19.8)	.39		
Gender			.85		
Male	148 (77%)	35 (75%)			
Female	45 (23%)	12 (26%)			
Race			1.00		
Non-white	40 (21%)	9 (16%)			
White	153 (79%)	38 (81%)			
Insurance (private/Medicare)			.63		
Private	89 (46%)	24 (51%)			
Medicare	104 (54%)	23 (49%)			
Deceased	58 (30%)	10 (21%)	.28		
OMP			.87		
No	106 (55%)	25 (53%)			
Yes	87 (45%)	22 (47%)			
Baseline audiogram	71 (37%)	46 (98%)	<.001*	75.4 (10.2-560.2)	<.001*
Tumor stage > IV	117 (58%)	25 (49%)	.41		
Cisplatin	131 (68%)	41 (87%)	.007*	2.7 (1.0-7.4)	.05*
Radiation	181 (94%)	44 (94%)	1.00		

Abbreviations: CI, confidence interval; OR, odds ratio.
[a]Mean (SD); n (%).
[b]Wilcoxon rank sum test; Pearson's χ^2 test; Fisher's exact test.
*$P < .10$ included in the logistic regression model, $P < .05$ considered statistically significant.

Table 4. Hearing Loss Characteristics by OMP

Characteristic, no. (%)	Pre-OMP, N = 131	Post-OMP, N = 109	*P* value[a]
Hearing loss identified	43 (33%)	44 (40%)	.41
Candidate for Hearing aid	36 (27%)	39 (36%)	.24
Sought treatment for hearing loss via hearing aid	14 (11%)	7 (6.4%)	.02

[a]Pearson's χ^2 test.

proactively detect changes in hearing and adjust chemotherapy regimens when medically appropriate.[13,14] Ototoxicity monitoring can be particularly challenging for patients as it requires coordination with chemotherapy infusion appointments, oncology clinic visits, and otolaryngology clinic visits; furthermore, monitoring may be hampered by other more severe treatment-related side effects that take priority over audiologic care. Consequently, it is unsurprising that pretreatment audiogram rates at institutions without an OMP have been observed to range from 24.3% to 39%.[11,12] Our study demonstrated a similar pretreatment audiogram rate of 34% prior to the start of the OMP. To address the lack of processes available to help patients access audiology services, many cancer centers have implemented various point-of-care strategies through OMPs. For example, Konrad-Martin et al created a protocol that uses mobile audiometry to screen patients for ototoxicity during cisplatin prehydration.[10] The main reasons for implementing a monitoring protocol are early detection and proactive management of hearing loss as well as improving patient follow-up. Our study demonstrated a marked improvement in audiologic follow-up with the implementation of an OMP; specifically, the proportion of patients that received a pretreatment audiogram increased to 66.1% ($P < .001$), and patients were found to be almost 7 times more likely to obtain a pretreatment audiogram compared to prior. This shift reinforces the conclusion that a structured monitoring system enhances patient follow-up with audiology.

Regular posttreatment monitoring is also essential to diagnose late-onset hearing changes and symptom progression. Permanent retention of cisplatin within the cochlea can result in progressive hearing changes that exceed those typically associated with age-related hearing loss.[3,15] Despite its impact on interpersonal relationships and social-emotional well-being, hearing loss is commonly overlooked by the impacted individual and consequently,

goes under-treated by health professionals.[16,17] In our study the OMP did not improve posttreatment monitoring and long-term follow-up; however, more patients reported otologic symptoms after the OMP was implemented. The proportion of patients receiving at least 1 posttreatment audiogram remained constant at approximately 20% both before and after the OMP, which was consistent with rates observed at institutions without an OMP, where rates range from 19.7% to 36%.[11] Our observed rate was also considerably lower than the 74.8% reported by Lee et al, where most cisplatin-treated patients enrolled in an OMP received at least 1 posttreatment audiogram. However, in their study, only 20.0% of patients had more than 1 audiogram, and just 22.1% of patients had an audiogram conducted after 6 months. The overall low participation in longitudinal surveillance reported across studies is concerning, as aural rehabilitation is the primary treatment for hearing loss. These findings suggest that the prevalence of treatment-related ototoxicity is likely underestimated and hearing loss is likely undertreated in the HNC population. Additional strategies are needed to address barriers to posttreatment and increase long-term ototoxicity monitoring to improve hearing-related quality of life in cancer survivorship.

A main objective of an OMP is to inform and treat cancer patients with treatment-related hearing loss. The standard of care before starting cisplatin chemotherapy includes patient education and aural rehabilitation, with guidance given on speech reading and compensatory communication strategies; if a hearing loss is identified patients should be evaluated and treated with amplification.[18] Hearing aid usage rates are rarely documented in the literature but have been reported to be as low as 24.8%.[12] Our study similarly found that hearing aid use at any point during follow-up among patients that were recommended amplification was 28%. Following the implementation of the OMP, there was an observed increase in patient-reported otologic symptoms, but the rate of patients using hearing aids decreased compared to before. This observation is likely because hearing aid utilization is influenced by multiple factors (ie, cost, stigma, severity of hearing loss), and the small sample size of this study limited additional analysis.

Nevertheless, other studies have clearly demonstrated that monitoring ototoxicity during cisplatin therapy results in higher rates of auditory rehabilitation. A randomized controlled trial by Konrad-Martin et al in 2021 compared hearing aid usage rates between cancer patients who underwent automated ototoxicity monitoring at a cisplatin infusion unit and those who were referred to audiology for a clinical audiogram. They found that within 1-year of treatment initiation, the rate of new hearing aid users was 37.5% (n = 6/16) in the audiology care cohort and 45.5% (n = 10/22) in the automated ototoxicity monitoring cohort. These findings indicate that early ototoxicity monitoring may encourage hearing aid utilization, potentially due to enhanced patient education and awareness of cisplatin ototoxicity.[19] The American Head and Neck Society head and neck survivorship consensus statement emphasizes the management of treatment-related ototoxicity and recommends that patients are evaluated yearly for hearing loss via pure tone audiometry for at least 2 years after treatment.[20] Despite this recommendation, maintaining consistent long-term audiologic follow-up continues to be a challenge; additional patient-oriented screening strategies are required to address the late ototoxic effects of cisplatin.

There are multiple limitations to the present study. First, because this study was conducted at a tertiary referral center, some patients may have chosen to follow up with a local audiologist, potentially underestimating the follow-up and hearing aid utilization rates observed. The OMP proposed by our study is dependent on our institution's infrastructure; therefore, the findings of this study cannot be generalized to other health systems without considering the contextual factors that could influence its applicability. However, it does provide evidence that a formal OMP improves patient care and should encourage other health systems to create their own monitoring strategies. Third, the increased likelihood of reporting otologic symptoms after implementing the OMP may be due to detection bias as the new protocol may affect how symptoms are noticed or documented, rather than indicating a true change in the frequency or nature of the symptoms. Finally, our study did not include patient quality of life measures or evaluate patient-facing barriers/attitudes toward obtaining audiologic care. Research involving cisplatin ototoxicity ultimately aims to improve cancer survivorship, so it is essential to consider patient perspectives in surveillance paradigms.

Conclusion

Implementation of an OMP significantly improved the proportion of HNC patients that underwent pretreatment audiograms prior to systemic therapy; however, audiologic follow-up and hearing aid utilization remained low during the posttreatment period. In the context of AAA and ASHA guidelines, adherence to cisplatin ototoxicity monitoring is poor. These findings emphasize the need for additional strategies for addressing long-term ototoxicity surveillance among HNC patients.

Author Contributions

Jena Patel, data collection, data analysis, manuscript preparation; **Jacob Beiriger**, data collection, manuscript preparation; **Kalena Liu**, data analysis, manuscript preparation; **Zach Urdang**, project conception, data collection; **Julia Croce**, project conception, data collection; **Molly Wolfson**, project conception, data collection; **Jacob Hulswit**, project conception, data collection; **Olivia Giglio**, project conception, data collection; **Jacob B. Hunter**, data analysis, manuscript preparation; **Irina Middleton**, project conception, data collection, manuscript preparation.

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