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Efficacy of Immune Checkpoint Inhibitors after Photoimmunotherapy for Head and Neck Cancer

Yukiomi Kushihashi[1,2*], Isaku Okamoto[3], On Hasegawa[4], Kunihiko Tokashiki[3], Kiyoaki Tsukahara[3], Tatsuo Masubuchi[1,2]

[1]Head and Neck Oncology Center, International University of Health and Welfare Mita Hospital, Tokyo, Japan
[2]Head and Neck Oncology Center, Chiba Nishi General Hospital, Matsudo, Japan
[3]Department of Otolaryngology-Head and Neck Surgery, Tokyo Medical University Hospital, Tokyo, Japan
[4]Department of Oral and Maxillofacial Surgery and Orthodontics, Tokyo Medical University Hospital, Tokyo, Japan
Email: *ykushihashi32@gmail.com

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Abstract

We conducted a multicenter study in collaboration with the Head and Neck Oncology Center of International University of Health and Welfare Mita Hospital and the Departments of Otolaryngology-Head and Neck Surgery and Oral and Maxillofacial Surgery/Orthodontics at Tokyo Medical University Hospital, and accumulated 40 cases (80 cycles) of head and neck photoimmunotherapy (PIT). Among these, we focused on 21 patients who received initiation or re-administration of immune checkpoint inhibitors (ICI) after PIT and performed a detailed analysis. The endpoints were overall response rate (ORR), disease control rate (DCR), complete response (CR) rate, overall survival (OS), progression-free survival (PFS) after ICI initiation, and progression-free survival 2 (PFS2), defined as the interval from the first PIT session to subsequent disease progression. The observed ORR, DCR, and CR rate after ICI initiation were 43.0%, 62.0%, and 19.0%, respectively. The median OS (mOS), median PFS (mPFS), and median PFS2 (mPFS2) were 14.3, 12.1, and 19.7 months, respectively. The median observation periods for OS, PFS, and PFS2 were 10.9, 4.3, and 10.8 months, respectively. In this study, favorable outcomes were obtained, suggesting that the introduction of ICI after PIT may represent an effective therapeutic strategy for unresectable locally advanced or recurrent head and neck cancer.

Keywords

Unresectable Locally Advanced or Recurrent Head and Neck Cancer, Photoimmunotherapy, Immune Checkpoint Inhibitor, Pembrolizumab, Nivolumab

1. Introduction

Over the past decade, the treatment paradigm for recurrent and/or metastatic head and neck cancer has changed dramatically. Historically, cure was rarely achievable, and palliative approaches, including systemic chemotherapy, radiotherapy, and best supportive care (BSC), constituted the mainstay of management. In Japan, however, the approval of the immune checkpoint inhibitor (ICI) nivolumab in 2017 brought about a major shift in therapeutic strategy. Subsequently, pembrolizumab, another ICI, was approved in 2019, followed by boron neutron capture therapy (BNCT) as a local treatment option in 2020 and photoimmunotherapy (PIT) in 2021 for unresectable locally advanced or recurrent head and neck cancer.

ICIs have become an important treatment option in the management of recurrent and/or metastatic head and neck cancer. As agents that modulate the cancer-immunity cycle, ICIs are characterized by lower toxicity compared with conventional cytotoxic chemotherapy, allowing their use even in elderly patients and in those with poor performance status (PS). Moreover, once a response is achieved, durable disease control can often be expected over a prolonged period [1].

Photoimmunotherapy is a novel modality that combines a monoclonal antibody conjugated to a photosensitive dye with irradiation at a specific wavelength. Upon illumination, the photosensitizer bound to the antibody undergoes structural changes, leading to rapid disruption of the cell membrane and exerting an antitumor effect. This form of cell death is considered immunogenic cell death and is thought to influence the cancer-immunity cycle. Several preclinical studies have reported that the combination of PIT and ICI is effective in enhancing antitumor immunity [2]-[4]. However, clinical studies on this combination are still ongoing, and its clinical efficacy remains unclear. Because PIT is expected to modulate the cancer-immunity cycle, it may affect subsequent systemic treatments. Indeed, there are several case reports demonstrating that the introduction of ICI after PIT resulted in complete response (CR) [5] [6]. Based on these considerations, we focused on patients who received ICIs after PIT.

In this multicenter retrospective study conducted at the Head and Neck Tumor Center of International University of Health and Welfare Mita Hospital and the Departments of Otolaryngology-Head and Neck Surgery and Oral and Maxillofacial Surgery/Orthodontics at Tokyo Medical University Hospital, we accumulated 40 patients (80 cycles) treated with PIT. Among them, we analyzed 21 patients who received initiation or re-administration of ICI after PIT and evaluated ORR, DCR, CR rate, OS, PFS after ICI, and PFS2 from the first PIT session.

2. Patients and Methods

2.1. Patients

The study population consisted of 21 patients with unresectable locally advanced or recurrent head and neck cancer who received initiation or re-administration of ICI after PIT between January 1, 2021 and August 31, 2024 (3 years and 8 months) at

the Head and Neck Tumor Center of International University of Health and Welfare Mita Hospital and the Departments of Otolaryngology-Head and Neck Surgery and Oral and Maxillofacial Surgery/Orthodontics at Tokyo Medical University Hospital.

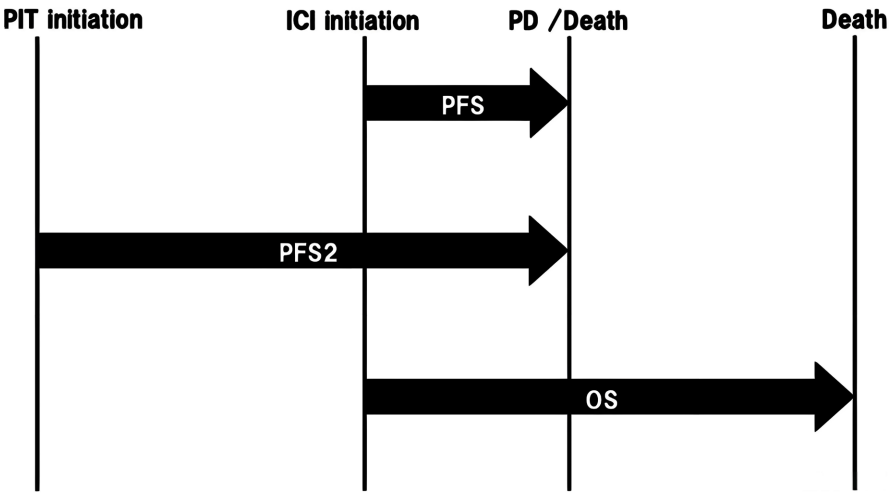
A retrospective review was conducted using the electronic medical records of both institutions.

19 patients in which rapid recurrence occurred after PIT and cytotoxic chemotherapy was selected, or in which ICI administration was not feasible due to transition to best supportive care (BSC), were excluded from the analysis.

2.2. Statistical Analysis

OS, PFS, and PFS2 were estimated using the Kaplan–Meier method, and statistical analyses were performed using EZR. The starting point for OS and PFS was defined as the date of ICI initiation, whereas the starting point for PFS2 was defined as the date of the first PIT session (Figure 1).

This study was approved by the Ethics Committee of International University of Health and Welfare Mita Hospital (Approval No. 5-24-63) and the Ethics Committee of Tokyo Medical University (Approval No. T2024-0065).



Schematic illustration showing the definitions of overall survival (OS), progression-free survival (PFS), and progression-free survival 2 (PFS2). PFS was defined as the interval from the initiation of immune checkpoint inhibitor (ICI) treatment to disease progression (PD) or death. PFS2 was defined as the interval from the first session of photoimmunotherapy (PIT) to subsequent disease progression (PD) or death. OS was defined as the interval from the initiation of ICI treatment to death from any cause.

Figure 1. Definition of OS, PFS, and PFS2.

3. Results

3.1. Patient Characteristics

The baseline characteristics of the 21 patients are summarized in Table 1. The age range was 40 - 81 years (median, 69 years), and the male-to-female ratio was 15:6.

The most common primary site was the oral cavity (6 patients, 28.7%), followed by the oropharynx (4 patients, 19.0%) and larynx (3 patients, 14.3%). Histologically,

Table 1. Patient characteristics.

Variable	n = 21
Age	40 - 81 years (median: 69 years)
Sex (Male:Female)	15:6
Primary Site	
Oral cavity (PIT to primary or perilesional lesion)	6 (Primary: 2; Perilesional: 3; Metastatic lymph node: 1)
Maxillary sinus (PIT to primary lesion)	2 (Primary: 2)
Oropharynx (PIT to primary or perilesional lesion)	4 (Primary: 3; Perilesional: 1)
Hypopharynx (PIT to perilesional lesion)	2 (Perilesional: 2)
Larynx (PIT to perilesional or metastatic lesion)	3 (Perilesional: 2; Metastatic lymph node: 1)
Nasal cavity/Paranasal sinus (PIT to primary lesion)	2 (Primary: 2)
External auditory canal (PIT to primary lesion)	2 (Primary: 2)
Histology (SCC:non-SCC)	20:1
Prior treatment*	Surgery: 15; RT or CRT: 21; ICI: 2
Number of PIT cycles	1 - 5 cycles (median: 2.0 cycles)
CPS (TPS)	NA: 4; 1 ≤ CPS < 20: 4; CPS ≥ 20: 12 (TPS < 1: 1)
ICI regimen (Monotherapy:Chemo-combination)	18:3

*Multiple prior treatments allowed.

20 patients had squamous cell carcinoma (SCC), and one patient had non-SCC (adenoid cystic carcinoma). In the non-SCC case, EGFR expression had been confirmed before PIT.

Prior treatments before PIT (not mutually exclusive) included surgery in 15 patients, radiotherapy alone or chemoradiotherapy in 21 patients, and previous ICI in 2 patients (1 nivolumab and 1 pembrolizumab).

Regarding PD-L1 expression, the combined positive score (CPS) was 1 ≤ CPS < 20 in 4 patients and CPS ≥ 20 in 12 patients. In one patient, only the tumor proportion score (TPS) was evaluated and was <1. PD-L1 testing was not performed in four patients, as tumor specimens were stored at other institutions and were not available.

The number of PIT sessions ranged from 1 to 5, with a mean of 2.2 and a median of 2.0. In Japan, PIT is reimbursed up to four sessions per primary lesion; however, one patient underwent five sessions in total because the lesions were judged to represent different primaries.

The interval from the last PIT session to ICI initiation ranged from 0.9 to 9.5 months, with a median of 2.1 months.

ICIs administered as the next treatment were used as monotherapy in 18 patients and in combination with chemotherapy in 3 patients. The combined chemotherapeutic agents were cisplatin (CDDP) and 5-fluorouracil (5-FU).

At the time of final follow-up, ICI treatment was ongoing in 8 patients, while 8 patients had switched to other chemotherapy regimens, all of which consisted of cetuximab plus paclitaxel. One patient transitioned to BSC, 2 patients had died,

and 2 patients were lost to follow-up due to transfer to other hospitals.

Two patients underwent ICI re-challenge following PIT. Both cases had initially shown resistance to ICI prior to PIT, and individual clinical courses are summarized as follows:

Case 1:

A patient with maxillary sinus carcinoma experienced local recurrence after chemoradiotherapy and subsequently received ICI therapy; however, the disease PD. Four cycles of PIT were performed, but local recurrence recurred again. ICI was re-administered after PIT, resulting in a PR.

Case 2:

A patient with tongue cancer developed delayed cervical lymph node metastasis after primary surgery and underwent additional neck dissection. Postoperatively, further cervical lymph node recurrence and multiple lung metastases were observed, and ICI was initiated. Although the lung metastases achieved CR, the cervical recurrence remained uncontrolled. Four cycles of PIT were performed, but cervical lymph node recurrence reappeared. Re-administration of ICI following PIT eventually led to a CR.

3.2. Best Response to ICI after PIT

The best responses to ICI after PIT are shown in Figure 2. CR was achieved in 4 patients (19.0%), partial response (PR) in 5 (24.0%), stable disease (SD) in 4 (19.0%), and progressive disease (PD) in 4 (19.0%). In 4 patients (19.0%), response evaluation was not available (NA) due to transfer and loss to follow-up.

Based on these results, the ORR was 43.0%, and the DCR was 62.0%.

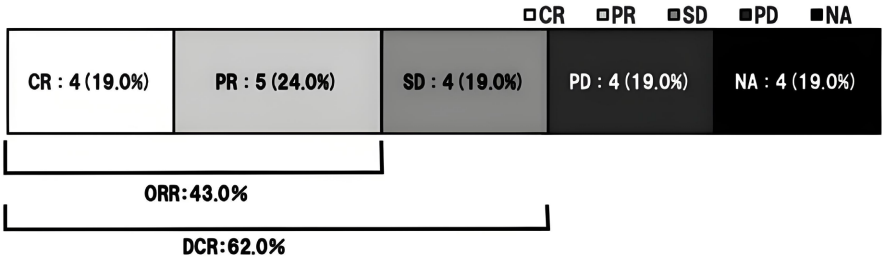
3.3. Survival Analysis

The median observation period was 10.9 months (range, 1.2 - 27.0 months). OS after ICI initiation is shown in Figure 3, and the estimated median overall survival (mOS) was approximately 14.0 months, based on the point at which the Kaplan–Meier curve crossed the 50% survival probability.

PFS and PFS2 are shown in Figure 4 and Figure 5, respectively. The estimated medians of PFS and PFS2 were approximately 12.1 months and 19.7 months, respectively, as calculated from the time points where each curve reached the 50% event probability. These values are reported as estimated medi**ans**, as the median follow-up duration was shorter than the estimated survival times, and therefore should be interpreted cautiously.

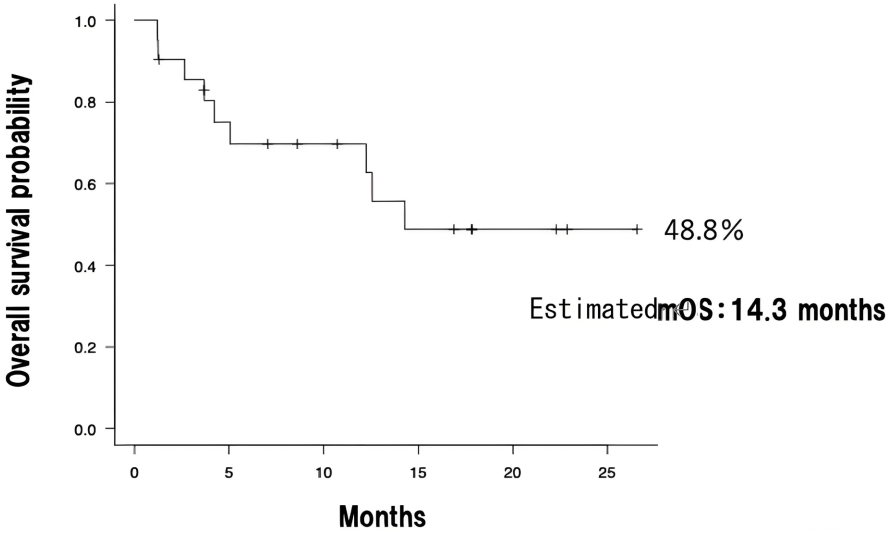
3.4. Safety Considerations

In our cohort, immune-related adverse events (irAEs) after ICI administration were observed in 4/21 patients (19.0%), including Grade 3 hepatic dysfunction (n = 1), Grade 2 hypothyroidism/endocrine dysfunction (n = 1), Grade 3 neuromuscular symptoms (n = 1), and gastrointestinal toxicity (Grade 1: n = 1; Grade 2: n = 1). No Grade 4 - 5 toxicities or treatment-related mortality were reported.



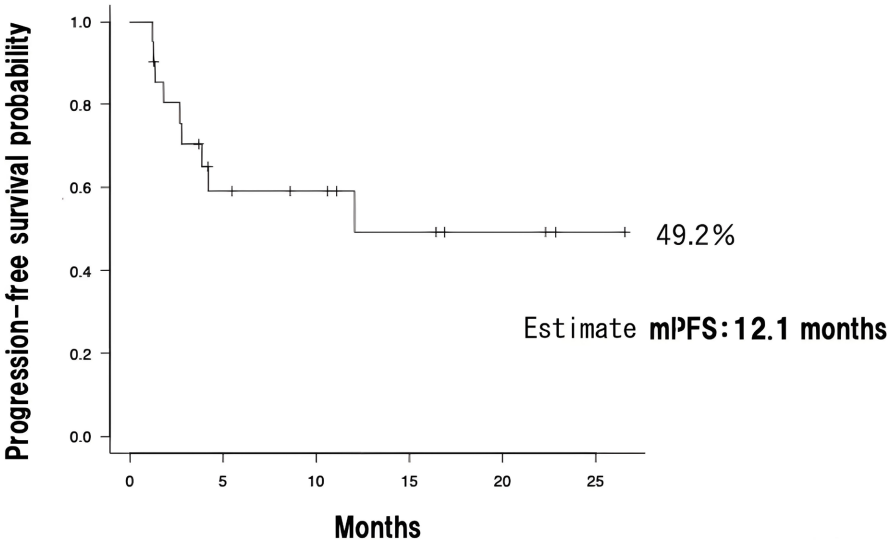
Best overall response (BOR) following ICI initiation. CR, PR, SD, PD, and NA are represented using five grayscale intensities and labeled within each bar. The legend is arranged horizontally above the graph. ORR: 43.0%; DCR: 62.0%.

Figure 2. Best overall response after ICI initiation.



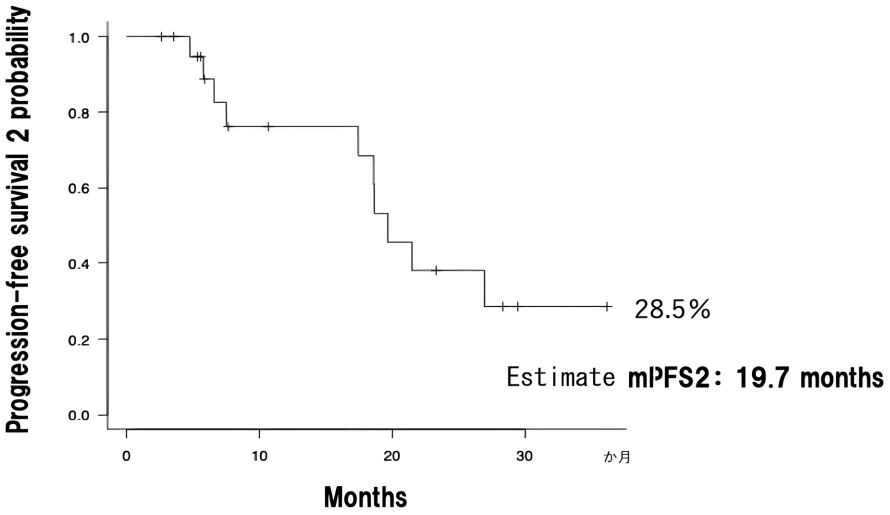
The estimated median OS (mOS) was 14.3 months, and the 1-year survival rate was 48.8%.

Figure 3. Overall survival (OS) after ICI initiation.



The estimated median PFS (mPFS) was 12.1 months, and the 1-year PFS rate was 49.2%.

Figure 4. Progression-free survival (PFS) after immune checkpoint inhibitor (ICI) initiation.



The estimated median PFS2 (mPFS2) was 19.7 months, and the 1-year PFS2 rate was 28.5%.

Figure 5. Progression-free survival 2 (PFS2) from the first photoimmunotherapy (PIT) session.

4. Discussion

In systemic therapy for head and neck cancer, platinum agents, fluoropyrimidines, and taxanes are used as cytotoxic chemotherapeutic drugs, cetuximab is used as a molecular-targeted agent, and nivolumab and pembrolizumab are available as ICIs. In particular, the advent of ICIs has been a major turning point in the treatment of head and neck cancer. In recurrent and/or metastatic disease, the use of these agents, either alone or in combination, and the strategy of employing as many effective regimens as possible over the disease course have improved survival outcomes.

The introduction of PIT into this evolving treatment landscape has further expanded therapeutic options. Although several preclinical reports have demonstrated the efficacy of combining PIT with ICIs, such combination therapy is not currently reimbursed in routine clinical practice [2]-[4]. In contrast, in the actual management of recurrent head and neck cancer, treatment is frequently modified in response to disease progression. Standard first-line systemic therapy typically involves ICIs, and in clinical practice, PIT as a local therapy is often followed by ICI as a subsequent systemic treatment. In the present study, even in patients previously treated with ICIs, some received a re-challenge with ICI after PIT. This reflects an attempt, within the context of limited treatment options for recurrent and/or metastatic head and neck cancer, to exploit the immunostimulatory effects of PIT to enhance the efficacy of ICI re-challenge.

In this study, the ORR, DCR, and CR rate after ICI initiation were 43.0%, 62.0%, and 19.0%, respectively, indicating very favorable outcomes. Although 3 patients received ICI in combination with chemotherapy and the sample size was relatively small (n = 21), thus precluding direct comparison, the ORR achieved in our cohort was superior to that reported for ICI monotherapy arms in the CheckMate-141,

KEYNOTE-040, and KEYNOTE-048 trials [1] [7] [8]. Furthermore, our results were comparable even with the chemo-combination ICI arm in the KEYNOTE-048 trial. Given that 12 of the 17 patients tested demonstrated a PD-L1 CPS ≥ 20, the high response rate observed in our cohort may reflect both PIT-related immune activation and favorable baseline tumor biology. Therefore, PD-L1 expression should be considered a potential confounding factor, and the therapeutic contribution of PIT alone cannot be conclusively determined in this retrospective study. These findings warrant cautious interpretation, and prospective studies will be required to validate whether PIT directly enhances subsequent ICI efficacy.

With respect to survival, the estimated mOS and estimated mPFS after ICI initiation were approximately 14.3 and 12.1 months, respectively, based on the points at which the Kaplan-Meier curves reached the 50% survival/event probability. These outcomes again appeared favorable when compared with the reported results of the above pivotal trials.

However, given that this study is a small-scale, retrospective analysis, any comparison with large randomized controlled trials such as KEYNOTE or CheckMate should be interpreted with caution, and the findings should not be regarded as evidence of direct equivalence.

Taken together, these findings suggest that the strategy of administering ICI after PIT may be effective, and that PIT could potentially enhance the therapeutic effect of subsequent ICI.

In animal models, the combination of PIT and ICI has been shown to enhance host antitumor immunity and augment the efficacy of ICI by promoting immune activation induced by PIT [2] [3]. To understand why PIT might enhance the efficacy of ICI, it is necessary to consider the influence of PIT on the "cancer-immunity cycle." The cancer-immunity cycle consists of seven steps: (1) release of cancer cell antigens, (2) presentation of cancer antigens by dendritic cells, (3) priming and activation of effector T cells, (4) trafficking of activated T cells to tumors, (5) infiltration of T cells into tumors, (6) recognition of cancer cells by T cells, and (7) killing of cancer cells [9].

PIT for head and neck cancer employs cetuximab sarotalocan sodium, an anti-EGFR antibody conjugated with IR700, which specifically binds to EGFR-expressing tumor cells. Upon irradiation with 690-nm red light, bound cancer cells are selectively destroyed [8] [10]. The destruction of tumor cells by PIT leads to the release of cancer antigens, which may promote activation of the cancer-immunity cycle. Dying tumor cells release damage-associated molecular patterns (DAMPs), which are key mediators of antitumor immune responses [11]. DAMPs activate dendritic cells, thereby inducing T-cell responses specific to tumor neoantigens and ultimately enhancing host antitumor immunity. In this context, PIT may influence steps (1), (2), and (7) of the cancer-immunity cycle, resulting in overall activation of the cycle and producing a synergistic effect with ICI.

In our cohort, there were two patients who had received ICI before PIT, suggesting that PIT may have overcome ICI resistance in these cases. ICIs act at step

(6) of the cancer-immunity cycle by blocking PD-L1-mediated immunosuppression and enhancing T-cell-mediated antitumor effects. In general, a higher PD-L1 CPS is associated with a better response to ICI [8]. However, in clinical practice, even tumors with high CPS are not uniformly sensitive, and many cases show ICI resistance. One potential explanation is that, even if step (6) is facilitated by ICI, other steps in the cancer-immunity cycle may be impaired. Possible mechanisms include strong immunosuppressive pathways other than PD-L1, insufficient tumor antigen availability leading to inadequate antigen presentation by dendritic cells, immunologically "cold" tumors that prevent infiltration of activated T cells, and T-cell exhaustion.

PIT may address some of these issues by inducing massive release of tumor antigens and enhancing antigen presentation, as well as by promoting the release of inflammatory cytokines that could alleviate T-cell exhaustion. Consequently, in cases where ICI alone failed to generate an adequate cancer-immunity cycle, PIT performed beforehand may "turn on" the cycle, thereby enabling a subsequent response to ICI.

Based on these observations, our findings suggest that a treatment strategy involving ICI re-administration after PIT may be effective even in tumors previously resistant to ICI.

Moreover, the administration of ICI after PIT did not result in an increased incidence of irAEs. However, given the retrospective nature, small sample size, and patient heterogeneity, these results should be interpreted with caution, and prospective studies are warranted to validate safety and efficacy.

The optimal sequencing of PIT and ICI remains an open question. PIT requires general anesthesia and is more invasive than systemic therapy alone. Therefore, from a practical standpoint, PIT should preferably be performed while the patient's general condition is still relatively preserved, and it is important not to miss the appropriate timing for this intervention.

Future perspectives will depend heavily on the accumulation of clinical data regarding the combination of PIT and ICI. In a phase Ib/II trial conducted in the United States that evaluated PIT in combination with pembrolizumab for recurrent and/or metastatic head and neck squamous cell carcinoma, no new safety concerns were identified for the combination therapy [12]. Based on these results, a global phase III trial (ClinicalTrials.gov ID: NCT06699212) is currently underway, and its results are eagerly awaited.

5. Conclusion

We analyzed ORR, DCR, CR rate, mOS, and mPFS after ICI initiation, as well as mPFS2 after PIT, in patients who received ICI following PIT. Our findings suggest that PIT may activate the cancer-immunity cycle and enhance the therapeutic effect of subsequent ICI. However, this study is limited by the small sample size (21 patients) and the inclusion of cases with relatively short follow-up periods. Further accumulation of cases and long-term observation are needed to validate these results.

Conflict of Interest

The authors declare no conflicts of interest related to this work.

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