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Management and nursing strategies for different patterns of adverse events in patients with urological cancer treated with immune checkpoint inhibitors

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Abstract

Background: This study aimed to explore the patterns of treatment-related adverse events (AEs) associated with immune checkpoint inhibitor (ICI) monotherapy and in combination with chemotherapy or tyrosine kinase inhibitor (TKI) therapy and to summarize the corresponding management and nursing strategies.

Materials and methods: A total of 69 patients with malignant urological tumors who received ICI treatment between June 2019 and October 2022 were retrospectively analyzed, and AEs that occurred during treatment were observed and reported. Based on the different types of treatment, the patients were divided into ICI monotherapy, ICI plus chemotherapy, and ICI plus TKI therapy groups. Subgroup analysis was performed. The incidence, distribution, and severity of AEs in the different subgroups were evaluated.

Results: A total of 138 AEs occurred in 69 patients, among which grade 1 plus 2, and grade 3 plus 4 AEs accounted for 78.99% and 21.01%, respectively. The incidence of AEs per patient in the ICI-TKI therapy group was the highest (3.75 times/person), followed by the ICI-chemotherapy (2.33 times/person) and ICI monotherapy (0.82 times/person) groups. Specific AEs, such as fatigue, nausea, and myelosuppression, were much more common in the ICI-gemcitabine and cisplatin group, whereas renal injury, skin lesions, and diarrhea were most common ones in the ICI-TKI group.

Conclusions: Immune checkpoint inhibitors are new treatment options for advanced urological tumors and renal cell carcinoma. Distinctive AE patterns were observed among the different treatment groups. Therefore, strict and meticulous clinical management and nursing measures are required to ensure the safety of patients receiving ICI treatment.

Keywords: Immune checkpoint inhibitor; Immunotherapy; Adverse events; Nursing; Urological tumor

1. Introduction

With the approval of pembrolizumab by the US Food and Drug Administration for the second-line treatment of advanced urothelial carcinoma in 2016, several immune checkpoint inhibitors (ICIs), such as programmed death protein-1/ligand-1 (PD-1/PD-L1), have been used clinically.[1] Immune checkpoint inhibitors are different from traditional chemotherapies that directly kill tumors. Immune checkpoint inhibitors prevent T cells from being switched off at several checkpoints, thus enhancing T cell–specific recognition and killing of tumors.[2]

In advanced urological cancer treatment, ICIs are widely used in the neoadjuvant, adjuvant, and salvage settings. For renal cancer, the combination of tyrosine kinase inhibitor (TKI) and PD-1/PD-L1 therapy is recommended as the first-line choice for advanced/metastatic renal cell carcinoma.[3,4] Programmed death protein-1/PD-L1 has been used as adjuvant, first-line maintenance, and second-line therapies for advanced/metastatic urothelial cancer.[5,6]

Owing to the widespread use of ICIs, immune-related adverse events (irAEs) have attracted increasing attention. Currently, the detailed mechanisms of irAEs are yet to be fully elucidated; however, it is known that irAEs involve multiple systems, with various manifestations and vast differences in severity. When multiple drugs are used in combination, confusion or mutual coverage usually occurs in adverse events (AEs), posing considerable challenges in the treatment and management of AEs.[7] Therefore, this study aimed to summarize the AEs of ICI monotherapy or combined use of PD-1 with chemotherapy or targeted therapies, conducting a statistical analysis of AEs in urologic cancers, which may facilitate early diagnosis or nursing management.

2. Materials and methods

2.1. Research objects

Patients with advanced/metastatic clear cell renal cell carcinoma and urothelial carcinoma who received PD-1 monotherapy or combination therapy and were admitted to the Peking University Third Hospital between June 2019 and October 2022 were retrospectively enrolled. All patients scored ≤2 according to the Eastern Cooperative Oncology Group criteria. All the patients signed an informed consent form (including informed consent for off-label use).

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2.2. Methods

Patients with advanced/metastatic renal cell carcinoma received TKI-targeted therapy combined with a PD-1 regimen as first-line therapy: axitinib (5 mg) orally, twice a day, combined with pembrolizumab (200 mg), toripalimab (240 mg), or tislelizumab (200 mg) intravenously every 21 days for a cycle. For patients with advanced/metastatic muscle-invasive urothelial cancers, if the creatinine clearance rate was less than 50 mL/min, PD-1 monotherapy was used as first-line or adjuvant therapy: pembrolizumab (200 mg), tislelizumab (200 mg), or toripalimab (240 mg) intravenously every 21 days for a cycle. For patients with urothelial cancer who can tolerate cisplatin, 6 cycles of "gemcitabine and cisplatin (GC)" chemotherapy followed by PD-1 maintenance therapy were administered: gemcitabine (1000 mg/m^2), cisplatin (70 mg/m^2) intravenous infusion on the first day, gemcitabine (1000 mg/m^2) combined with pembrolizumab (200 mg), tislelizumab (200 mg), or toripalimab (240 mg) intravenous infusion on the eighth day every 3 weeks.

2.3. Efficacy and safety evaluation

All patients underwent safety evaluations at the end of each cycle, including digestive, urinary, endocrine, respiratory, circulatory, skeletal, muscular, hematological, and skin conditions. Several aspects were observed and recorded, including the occurrence time, duration, nursing intervention, corresponding management, and prognosis of AEs. All AEs or serious adverse events (SAEs) were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.[8] Serious adverse events were defined as any medical occurrence that resulted in death, life-threatening, required hospitalization, prolonged existing hospitalization, caused persistent or significant disability or incapacity, or was an important medical event. The details of the National Cancer Institute Common Terminology Criteria for Adverse Events grading system are provided in Supplemental Digital Content (Supplementary Table 1, http://links.lww.com/CURRUROL/A44). Follow-up data were obtained through outpatient clinic visits or telephone follow-ups. Tumor assessments were performed at screening and at the end of every 3 cycles (±1 week) from the first dose according to the criteria of Response Evaluation Criteria in Solid Tumours (RECIST) 1.1 version.[9] A standard operating procedure for recording and reporting all AEs is proposed in the supplementary information according to actual clinical experience (Supplemental Digital Content, Supplementary Table 2, http://links.lww.com/CURRUROL/A44).

2.4. Statistical analysis

All AEs were summarized and reported according to the organ system, treatment category, and preferred terms. We compared the patients among 3 groups using the t test for continuous variables and χ^2 test for categorical variables. One-way analysis of ANOVA test was applied to multiple groups. IBM SPSS version 27 statistical package (SPSS Inc., Chicago, IL, USA) and GraphPad Prism 9.4 (GRAPHPAD SOFTWARE, LLC., California, USA) were used for statistical analysis and graph drawing. A 2-sided p value of <0.05 was considered significant.

3. Results

3.1. General information

A total of 69 patients were enrolled between June 2019 and October 2022. There were 48 men and 21 women in the cohort, with an average age of 73.6 years (ranging from 26 to 81 years). Among the 69 patients, 34 received PD-1 monotherapy (the ICI Mono group), 15 received PD-1 with gemcitabine-cisplatin chemotherapy (the ICI-GC group), and the other 20 received PD-1 with TKI (axitinib) targeted therapy (the ICI-TKI group). Table 1 shows the baseline demographic and clinical characteristics. At the research cutoff point (October 2022), the median follow-up period was 11 months.

Among all enrolled patients, 69.57% (48 of 69) experienced treatment-related AEs of any grade, and 30.43% (21 of 69) experienced SAEs. No grade 5 SAEs were observed in either group. A total of 138 AEs occurred with an average of 1.65 times per

Table 1

Baseline demographic and clinical characteristics of treated patients.

Variable	ICI mono (n = 34)	ICI-GC (n = 15)	ICI-TKI (n = 20)	Overall (n = 69)	p
Sex					0.683*
Men	21	10	3	48	
Women	13	5	17	21	
Age, yr					
Mean (range)	71.5 (62–81)	78.7 (56–78)	68.1 (26–79)	73.6 (26–81)	0.774†
Tumor type					
UC	33	15	0	48	0.000*
RCC	1	0	20	21	
PD-1 type					0.451*
Pembrolizumab	10	4	7	21	
Tislelizumab	15	6	6	27	
Toripalimab	9	5	7	21	
Average cycle					
Mean (SD)	8.35 (4.54)	8.67 (3.9)	9.85 (7.35)	9.14 (3.9)	0.512**
Response					
CR	12	5	2	19	0.121*
PR	3	8	8	19	
SD	14	1	4	19	
PD	5	1	6	12	

CR = complete response; GC = gemcitabine and cisplatin; ICI = immune checkpoint inhibitor; Mono = monotherapy; PD = progressive disease; PR = partial response; RCC = renal cell carcinoma; SD = stable disease; TKI = tyrosine kinase inhibitor; UC = urothelial carcinoma.

*One-way ANOVA test. **student t-test.

†Student t test.

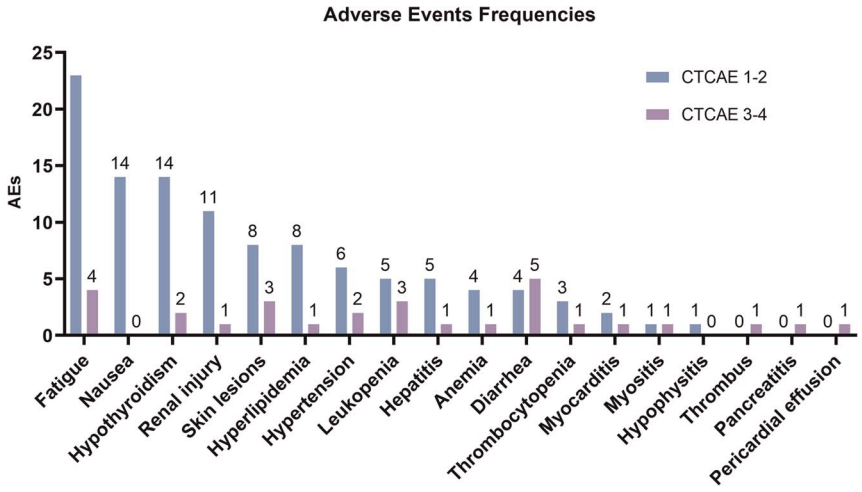

Figure 1. All adverse events are listed in descending order by frequencies. CTCAE = Common Terminology Criteria for Adverse Events.

person. Among all age groups, 109 AEs were grades 1 and 2 (78.99%), whereas the remaining 29 AEs were grades 3 and 4 (21.01%). The most common treatment-related AEs were fatigue, nausea, hypothyroidism, renal injury, and skin lesions. The details of the AEs are shown in Figure 1.

3.2. Subgroup analysis of irAEs

We performed a comparative analysis of treatment-related AEs in all patients according to the treatment regimen. In terms of frequency of occurrence, the overall incidence of AEs in the ICI-TKI group was the highest, followed by that in the ICI-GC group, which was higher than that in the PD-1 monotherapy group (Table 2 and Fig. 2A).

Table 2

Comparative analysis of AEs in 3 subgroups.

	Treatment group					
	ICI mono (n = 34)		ICI-GC (n = 15)		ICI-TKI (n = 20)	
Treatment-related AE, n	All grades	Grade 3 or 4	All grades	Grade 3 or 4	All grades	Grade 3 or 4
Total patients with an AE	16	5	13	6	19	10
Fatigue	10	1	10	2	7	1
Nausea	0	0	8	0	6	0
Hypothyroidism	5	1	2	0	9	1
Renal injury	1	0	2	0	9	1
Skin lesions	2	1	2	0	7	2
Hyperlipidemia	2	0	0	0	7	1
Hypertension	0	0	0	0	8	2
Leukopenia	0	0	6	3	2	0
Hepatitis	0	0	0	0	6	4
Anemia	1	0	1	0	3	1
Diarrhea	1	1	2	0	6	4
Thrombocytopenia	1	0	1	0	2	1
Myocarditis	0	0	0	0	1	1
Myositis	1	1	0	0	1	0
Thrombus	1	1	0	0	0	0
Pancreatitis	0	0	1	1	0	0
Pericardial effusion	0	0	0	0	1	1
Hypophysitis	1	0	0	0	0	0

AE = Adverse events; GC = gemcitabine and cisplatin; ICI = immune checkpoint inhibitor; Mono = monotherapy; TKI = tyrosine kinase inhibitor.

We calculated the frequency of complications in individual patients within each group (ie, the total frequency of AEs per person). The incidence of AEs in the PD-1 monotherapy group (0.82/person) was lower than those in the PD-1 combination chemotherapy (2.33/person) and PD-1–TKI (3.75/person) groups. There were statistically significant differences between every 2 of the 3 groups ($p < 0.05$) (Fig. 2B).

3.3. AE aggregation pattern analysis

An AE distribution matrix was generated to explore the distribution pattern of AEs in each treatment group (Fig. 3). Patients who received the same treatments were grouped. By observing the color block aggregation pattern, we found that (1) fatigue, nausea, and myelosuppression were more common in the ICI-GC group, suggesting that the adverse effects of chemotherapy and (2) renal injury, skin lesions, diarrhea, and hepatitis were more likely due to the TKI regimen.

4. Discussion

Urological tumors account for a substantial proportion of all new tumors. Kidney and urothelial cancers accounted for 4.12% and 7.44% of new cancers per year, respectively.[10] Although radical surgery remains the primary method for treating local-stage tumors, many tumors still "escape" immune system surveillance before surgery, remaining in hidden reservoirs waiting for postoperative recurrence and progression. In single-use or combination therapies, ICIs are widely used in second-line, first-line, and adjuvant therapies. Accordingly, the AEs related to immunotherapy have attracted increasing attention.

Programmed death protein-1 is mainly distributed on the surface of killer T cells (CD8+), and its ligand, PD-L1, is highly expressed on the surface of multiple types of tumors. When PD-1/PD-L1 binds to its ligand PD-L1, the immunoreceptor tyrosine switch site in the intracellular segment of PD-1/PD-L1 is activated, resulting in the silencing of T cells, which in turn promotes tumor "immune escape".[11] However, the use of PD-1/PD-L1 inhibitors has a certain probability of causing abnormal activation of the immune system and induction of a T cell antihost response, which is one of the leading causes of irAEs.[12] Immune-related adverse events related to urological tumors involve a wide range of systems, with multiple

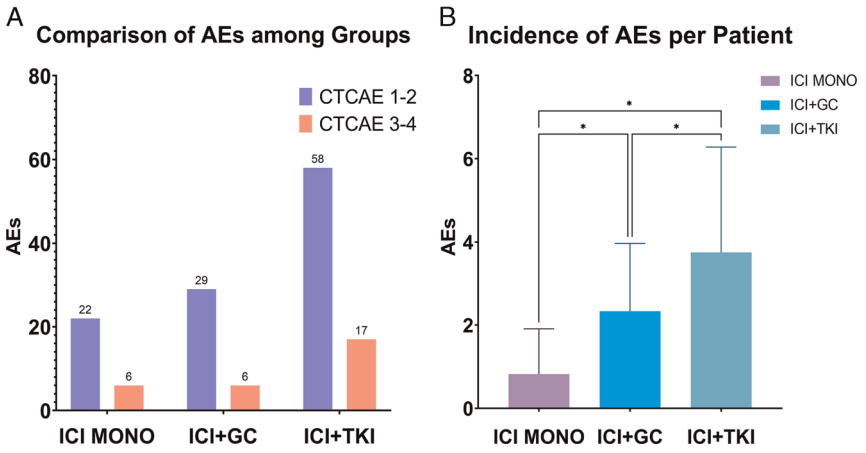

Figure 2. Subgroup analysis of irAEs. (A) All types of AEs in the ICI Mono group were lower than those in the ICI-GC and ICI-TKI groups. (B) Comparing the frequency of AEs per patient, the ICI Mono group was lower than the ICI-GC group and lower than the ICI-TKI group, and statistical differences were found between the groups. *$p < 0.05$; One-way ANOVA test was applied among multiple groups. AE = adverse event; ANOVA = analysis of variance; CTCAE = Common Terminology Criteria for Adverse Events; GC = gemcitabine and cisplatin; ICI = immune checkpoint inhibitor; irAE = immunotherapy-related adverse event; MONO = monotherapy; TKI = tyrosine kinase inhibitor.

clinical manifestations and varying degrees of severity, and are very likely to be confused with AEs associated with chemotherapy or TKI agents.

4.1. Immune-mediated hepatitis

Immune-mediated hepatitis (IMH) induced by ICI differs from the specific liver damage directly caused by traditional drugs, and T cell-induced indirect liver injury is more similar to autoimmune hepatitis.[13] It is mainly characterized by elevated aspartate transaminase and alanine transaminase levels, with or without elevated bilirubin or alkaline phosphatase levels. Patients with grade 1 IMH can continue ICI treatment, and their hepatic function can be monitored weekly. For grade 2 cases, prednisone 0.5 mg/kg/d should be added with or without an ICI pause. Immune checkpoint inhibitor should be stopped in grades 3 and 4 cases, and intravenous glucocorticoids should be considered. Mycophenolate mofetil, tacrolimus, and other treatments are optional treatments.[14] In some IMH cases, the decrease in bilirubin levels is often delayed compared with the relief of liver enzymes. Patients must be fully informed of the management and recovery processes.

4.2. Immune-related skin and mucous membrane damage

Immune checkpoint inhibitor–mediated skin damage manifests in various forms including exanthematal eruptions, skin pruritus,

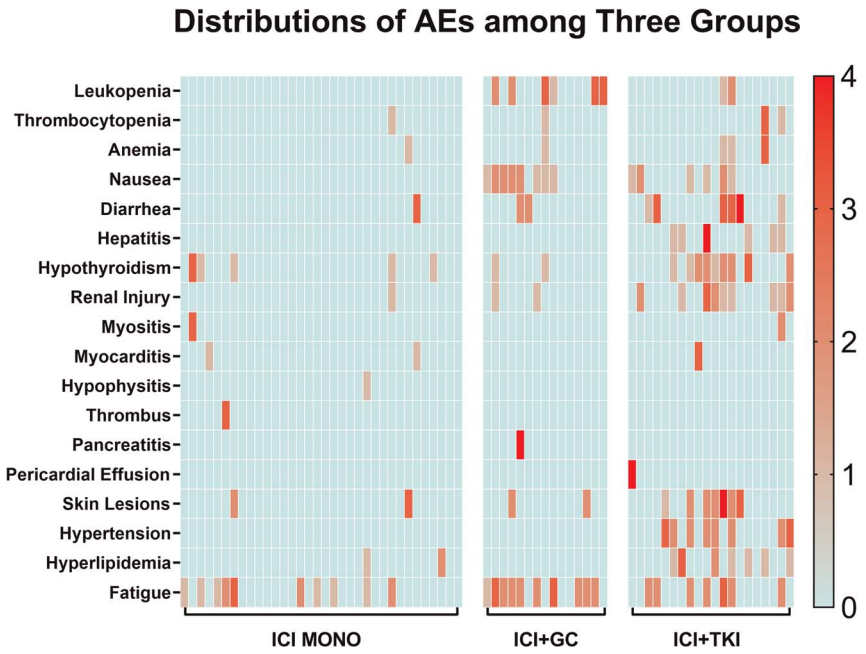

Figure 3. Distribution heat map of AEs. Distribution patterns of AEs in each group could be observed by aggregation concentrations of the red color blocks. AE = adverse events; GC = gemcitabine, cisplatin; ICI = immune checkpoint inhibitor; MONO = monotherapy; TKI = tyrosine kinase inhibitor.

lichenoid changes, erythema multiforme, and connective tissue disease-like reactions. Generally, it is essential to guide patients in discovering and reporting skin or mucosal changes. For grades 1 and 2 skin irAEs, topical emollients and glucocorticoid ointments relieve the symptoms. Oral corticosteroids are required for grades 3 and 4 cases, and dermatologist consult is preferred for differential diagnosis, and ICI should be discontinued if necessary. Notably, some ICIs have been reported for specific skin lesions, such as those that induce reactive cutaneous capillary endothelial proliferation (RCCEP), which is usually prone to ulceration and bleeding.[15] Two patients with renal cell carcinoma in our cohort had RCCEP and received ICI-TKI therapy (Fig. 4A). Patients must be informed that RCCEP can occur in the oral or nasal cavity or conjunctiva. Therefore, rubbing and scratching should be avoided. The application of glucocorticoid ointment was helpful for symptom control in these patients. In addition, vitiligo-like lesions are highly associated with a good response to ICI treatment (Fig. 4B), which is rarely observed with pure TKI therapy or chemotherapy.[16]

4.3. Gastrointestinal-related AEs

The clinical manifestations of gastrointestinal AEs mediated by immunotherapy are relatively diverse, with hiccups, anorexia, diarrhea, or colitis being the most common. Distinguishing immune-related digestive AEs from TKI-related AEs is challenging. Long-segment edema of the bowel mucosa is more typical in ICI cases, with significant lymphocyte infiltration according to biopsy findings.[17] The clinical management is similar to that of immune hepatitis.[18] In daily nursing evaluations, more attention should be paid to abdominal symptoms, stool shape, and defecation habits. Computed tomography scans should be performed promptly for patients with positive symptoms such as bloody stools or signs of intestinal obstruction.[19] Immunodeficiency-related pancreatitis is a rare condition. One patient of urothelial carcinoma in our cohort experienced very insidious pancreatitis. The patient had abdominal pain and diarrhea, and the amylase and lipase levels progressively increased. The patient recovered after receiving parenteral nutrition and intravenous somatostatin for 2 weeks.

4.4. Endocrine-related AEs

The most common types of endocrine-related irAEs include hyperthyroidism and hypothyroidism, similar to the shift from the early to middle stages of Hashimoto disease. Patients usually develop hyperthyroidism early and then develop hypothyroidism in the late stages.[20] Grade 1 hypothyroidism does not require treatment. When thyrotropin is >10 IU/L in grades 2 and 3, thyroxine must be supplemented. In grade 4, ICI should be stopped immediately, and an endocrinologist's consultation is preferred. Patients must be guided to monitor several basic signs such as heart rate, fatigue level, body weight, and basic metabolic rate.

4.5. Other types of irAEs

In our cohort, 1 case of asymptomatic myocarditis was reported, manifesting as a level 2 increase in Creatine Kinase MB in cycle 2 with S-T segment depression on electrocardiography, which resolved spontaneously after prolonging the interval of ICI treatment. In addition, 1 patient developed myositis with severe fatigue. The serum creatine kinase was 10 times higher than the normal threshold. Symptoms were relieved entirely after a 2-week application of oral prednisone (10 mg, twice a day). Unlike in previous reports, none of the patients in our cohort exhibited immune-related pneumonia.

4.6. Limitations

The current study has some limitations. Only 69 patients were enrolled in this study. A small cohort would cause accidental bias in the results. Patients with renal cell carcinoma and urothelial carcinoma were included in the data analysis. Thus, the primary tumor type cannot be ruled out as a cause of the AEs. More detailed records of AEs need to be considered for a comprehensive analysis, such as the initiation time point and duration of each AE.

5. Conclusions

Immune checkpoint inhibitors are new treatment options for advanced urological tumor and renal cell carcinoma. Distinctive

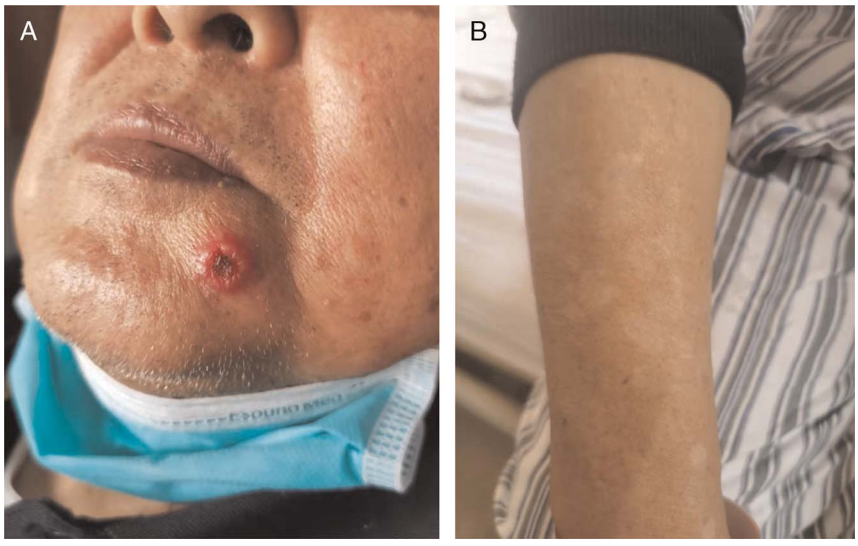

Figure 4. Immune checkpoint inhibitor–related cutaneous irAEs. (A) Reactive cutaneous capillary endothelial proliferation; (B) Vitiligo-like lesions associated with ICIs. ICI = immune checkpoint inhibitor; irAEs = immunotherapy-related adverse events.

patterns of AE manifestations were observed in the different treatment groups. Thus, corresponding precautionary strategies and nursing management can be provided in advance. Strict and meticulous clinical management and nursing measures are required to ensure the safety of patients receiving ICI treatment.

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None.

Statement of ethics

Ethical approval for the study was obtained from the ethnic committee of Peking University Third Hospital, with an approval number S2021259. Informed consent was obtained from all individual participants included in the study. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest statement

No conflict of interest has been declared by the authors.

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None.

Author contributions

XH: Conceptualization, methodology, data curation, visualization, data collection, writing – original draft;
XL: Formal analysis, validation, data collection, writing – review & editing;
LM: Project administration, supervision;
CL: Conceptualization, methodology, project administration, supervision.

Data availability

The datasets generated during and/or analyzed during the current study are not publicly available, but are available from the corresponding author on reasonable request.

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