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Cost-utility analysis of durvalumab combined with tremelimumab as a first-line treatment for advanced unresectable hepatocellular carcinoma

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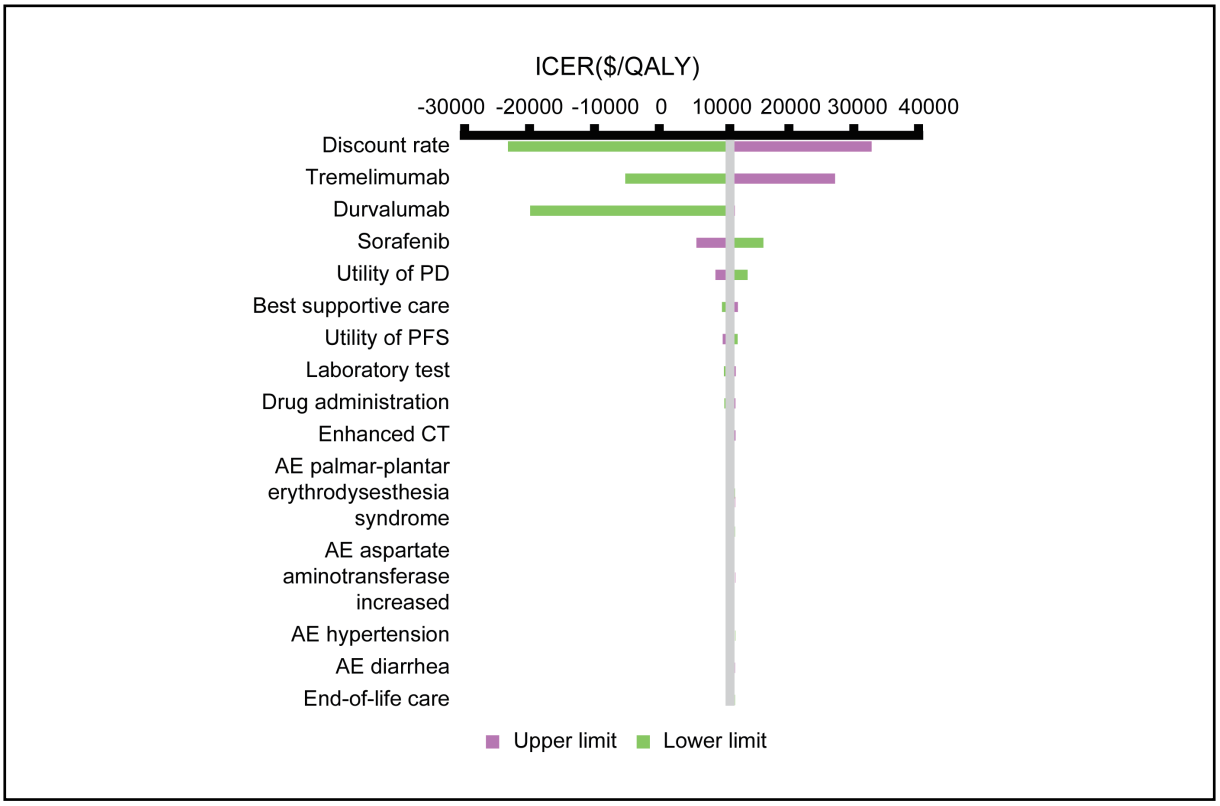
Graphical abstract



The OWSA results indicate that the discount rate and cost of tremelimumab and durvalumab have a major impact on the ICER.

Public summary

- This study is the first to evaluate the cost–effectiveness of durvalumab combined with tremelimumab as a first-line treatment for uHCC from the perspective of China's healthcare framework via a partitioned survival model.
- The results show that the ICER of durvalumab combined with tremelimumab is more cost effective than that of sorafenib alone.
- The high cost of tremelimumab significantly affects the cost-effectiveness of the STRIDE regimen.

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Abstract: *Objective*: This study aimed to evaluate the cost–effectiveness of durvalumab combined with tremelimumab versus sorafenib as the first-line treatment for advanced unresectable hepatocellular carcinoma (uHCC) from the perspective of China's healthcare system. *Methods*: Utilizing data from the HIMALAYA clinical trial, a partitioned survival model was developed to simulate clinical pathways, costs, and outcomes. Incremental cost–effectiveness ratios (ICERs) were calculated through cost–utility analysis, with robustness assessed via one-way and probabilistic sensitivity analyses. *Results*: Total costs for the durvalumab–tremelimumab regimen reached 152,729.04 USD (1.96 quality-adjusted life years, QALYs), whereas they reached 147,406.75 USD (1.48 QALYs) for sorafenib. The ICER of 11,027.79 USD per QALY remained substantially below China's willingness-to-pay (WTP) threshold of 36,622.13 USD per QALY. Sensitivity analyses confirmed tremelimumab pricing and discount rates as primary determinants of cost–effectiveness. *Conclusion*: Within China's healthcare framework, durvalumab–tremelimumab is cost effective as a first-line therapy for uHCC, contingent on formulary inclusion and price adjustments.

Keywords: cost–effectiveness analysis; unresectable hepatocellular carcinoma; PD-1 inhibitors

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1 Introduction

Hepatocellular carcinoma (HCC) is one of the most common malignant tumors[1]. The pathogenesis of HCC is related mainly to liver cirrhosis and viral hepatitis. China represents a high-burden region for HCC[2], with incidence and mortality rates ranking 4th and 2nd among malignancies nationally, exceeding global averages[3]. Some early HCC patients can be treated via surgical resection, local ablation, or liver transplantation. However, most patients are in serious condition when diagnosed with HCC due to the lack of obvious symptoms and the insidious nature of the disease. Advanced HCC patients develop large-diameter liver tumors, decompensated cirrhosis, and the spread of cancer cells, making radical treatment unavailable[4]. The prognosis for advanced HCC patients is extremely poor, with a 5-year survival rate of less than 10%[5].

In 2007, sorafenib received FDA approval as the initial targeted therapy for unresectable hepatocellular carcinoma (uHCC) first-line treatment, but its efficacy and overall survival (OS) benefits remain limited[6]. In recent years, several clinical studies have explored the efficacy and safety of combining programmed cell death protein 1 (PD-1) inhibitors with targeted therapies for uHCC[7]. Preliminary results have shown that this combination treatment has significant antitumor activity and efficacy in the treatment of uHCC, potentially changing the treatment strategy and prognosis[8].

Recently, a randomized, open-label, multicenter phase III HIMALAYA trial showed that the combination of the PD-1 inhibitor durvalumab and the cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) inhibitor tremelimumab had a median overall survival (mOS) of 16.43 months compared with 13.77 months for sorafenib monotherapy in patients with uHCC, with a median progression-free survival (PFS) of 3.78 months versus 4.07 months[9]. The "Primary Liver Cancer Diagnosis and Treatment Guidelines (2022 Edition)" recommend durvalumab combined with tremelimumab as a Grade I expert recommendation and Level 1A evidence[10]. This study aimed to assess the cost–effectiveness of the combination of durvalumab and tremelimumab compared with sorafenib monotherapy for unresectable hepatocellular carcinoma from the viewpoint of China's healthcare system. The partitioned survival (PS) model was used to compare costs and outcomes. This study provides a reference for selecting more cost-effective first-line treatment options and reducing the financial burden on patients.

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2 Materials and methods

2.1 Materials

Patient data and treatment information were consistent with those of the HIMALAYA study, which included 782 previously untreated HCC patients, with 393 in the durvalumab combined with tremelimumab group and 389 in the sorafenib group. The inclusion and exclusion criteria were the HIMALAYA phase III clinical trial. The STRIDE group (durvalumab combined with tremelimumab) was treated as follows: a 4-week treatment cycle, with 1500 mg of durvalumab and 300 mg of tremelimumab in the first cycle, followed by 1500 mg of durvalumab every cycle. The sorafenib group was treated with 400 mg of sorafenib twice daily. Treatment continued until death, intolerable toxicity, withdrawal of consent, or other protocol-specific reasons. Second-line anticancer therapy was applied in the STRIDE group (40.7% of the patients) and in the sorafenib group (45.0% of the patients). This finding is consistent with the results of the HIMALAYA study (see Supporting information). The best supportive care was administered to the remaining patients.

2.2 Model design

A PS model was developed to simulate uHCC disease trajectories, incorporating three mutually exclusive health states, progression-free survival (PFS), progressive disease (PD), and terminal death, which are linked by predefined transition pathways (Fig. 1). All cohort members initiated in the PFS state, with transitions restricted to forward movement between states per 4-week cycle. The death state functions as an absorbing node, prohibiting reverse transitions[11]. The simulation spanned patient lifetimes, terminating when ≥99% of both cohorts reached mortality. The key endpoints included cumulative costs, quality-adjusted life years (QALYs) gained, and incremental cost–effectiveness ratio (ICER) values. Following the "China Guidelines for Pharmacoeconomic Evaluation (2020)", the willingness-to-pay (WTP) threshold was determined to be three times the per capita GDP[12]. In 2023, China's per capita GDP was 89,358 CNY, translating to a WTP threshold of 268,074 CNY/QALY (36,622.13 USD/QALY) for this research. Both costs and utilities were discounted at a rate of 5%[12], and a half-cycle correction was implemented.

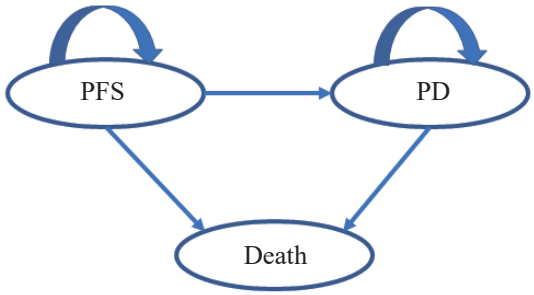

Fig. 1. Three-state partition survival model.

2.3 Survival analysis

The survival curve data from the HIMALAYA study were retrieved through the use of the GetData Graph Digitizer. The individual patient data were subsequently reconstructed via R4.2.2 software. To fit and extrapolate the survival curves, several parametric distributions were employed, including the exponential, gamma, Gompertz, Weibull, log-logistic, and log-normal distributions[13]. The selection of the most suitable fitting distribution was based on two key criteria: the Akaike information criterion (AIC) and the Bayesian information criterion (BIC), as presented in Table 1. As shown in Table 2, for the STRIDE group, both the OS curve and the PFS curve were best fitted by the log-normal distribution. In the case of the sorafenib group, the PFS curve was also fitted by the log-normal distribution, whereas its OS curve was optimally fitted by the log-logistic distribution. Fig. 2 shows the overall

Table 1. AIC and BIC values of the survival curve fitting distribution.

Fitting criterion	KM curve	Exponential distribution	Gamma distribution	Gompertz distribution	Weibull distribution	Log-logistic distribution	Log-normal distribution
AIC	STRIDE OS	2259.778	2261.381	2251.532	2260.269	2245.581	2240.865
	Sorafenib OS	2364.539	2365.572	2365.761	2366.254	2359.564	2363.245
	STRIDE PFS	2178.758	2178.159	2098.373	2166.130	2058.706	2055.584
	Sorafenib PFS	2004.856	2002.140	1997.662	2006.456	1952.163	1950.265
BIC	STRIDE OS	2263.752	2269.329	2259.479	2268.216	2253.528	2248.812
	Sorafenib OS	2368.502	2373.499	2373.499	2374.181	2367.491	2371.172
	STRIDE PFS	2182.732	2186.107	2106.321	2174.077	2066.653	2063.532
	Sorafenib PFS	2008.819	2010.067	2005.589	2014.384	1960.090	1958.192

Table 2. Optimal fitting distribution and parameters of the survival curve.

Survival curve	Optimal fitting distribution	Mean/shape parameter	Standard deviation/scale parameter
STRIDE OS	Log-normal	2.85885	1.42108
Sorafenib OS	Log-logistic	1.36464	13.58088
STRIDE PFS	Log-normal	1.60220	1.14796
Sorafenib PFS	Log-normal	1.48977	1.04155

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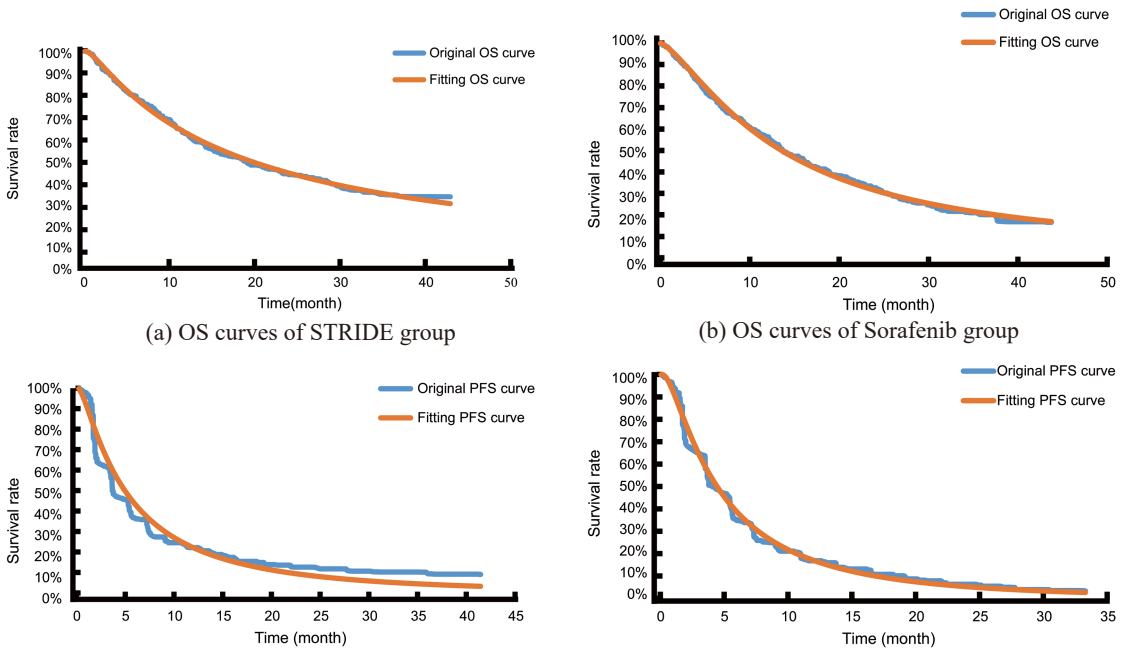

(a) OS curves of STRIDE group

(b) OS curves of Sorafenib group

(c) PFS curves of STRIDE group

(d) PFS curves of Sorafenib group

Fig. 2. OS curves and PFS curves before and after model fitting.

survival and progression-free survival curves for the two treatment regimens, both before and after model fitting.

2.4 Costs and utilities

This research was carried out from the standpoint of China's healthcare framework. It takes into account solely direct medical expenses, which cover drug costs, costs for best supportive care, drug administration costs, laboratory test costs, enhanced CT costs, end-of-life care costs, and costs for adverse event management. Drug administration costs included intravenous injection fees, diagnostic test fees, and bed fees. The laboratory tests included hematology, urinalysis, blood biochemistry, coagulation parameters, thyroid function, and alpha-fetoprotein tests. The drug costs were obtained from YAOZH.COM (www.yaozh.com). For this study, the patient's body weight was assumed to be 65 kg, corresponding to a body surface area of 1.72 m^2. Only grade 3 or higher severe adverse events were considered. The exchange rate between the Chinese Yuan and the US Dollar in December 2024, which was 1 USD= 7.32 CNY, as provided by the National Bureau of Statistics of China, was applied in this research.

In the STRIDE group, the incidence rates of diarrhea, aspartate aminotransferase elevation, and hypertension were 4.4%, 5.2%, and 1.8%, respectively. In the sorafenib group, the rates of diarrhea, aspartate aminotransferase elevation, hand–foot skin reaction, and hypertension were 4.3%, 3.2%, 9.1%, and 6.1%, respectively. It was assumed that adverse events occurred once within the first cycle. The utility values were sourced from the relevant literature[14]. The model parameters and their distributions are presented in detail in Table 3.

2.5 Sensitivity analysis

To evaluate the robustness of the results, both one-way sensitivity analysis (OWSA) and probabilistic sensitivity analysis (PSA) were performed. The OWSA aims to gauge the influence of individual parameters on the ICER. For parameter variation, 95% confidence intervals were utilized as the upper and lower bounds. In cases where confidence intervals were not accessible, a range of ±20% of the basic value was adopted. Given that durvalumab is included in China's medical insurance coverage, its upper limit was fixed at the basic value, whereas the lower limit was set at 80% of the base-case value. The findings of the OWSA are depicted in a tornado diagram.

The PSA was employed to examine the impact of the concurrent variation in multiple parameters on the outcomes. Specifically, the cost parameters adhered to the Gamma distribution, and the utility values, along with the discount rates, followed the Beta distribution. The PSA results are presented in cost–effectiveness scatter plots and cost–effectiveness acceptability curves.

3 Results

3.1 Basic analysis

The results are shown in Table 4. The STRIDE group (durvalumab plus tremelimumab) had 0.48 more QALYs than did the sorafenib group, with an additional cost of 5,322.28 USD. The ICER was 11,027.79 USD/QALY, below the WTP threshold of 36,622.13 USD/QALY, indicating that durvalumab combined with tremelimumab is more cost effective than sorafenib as a first-line treatment for uHCC.

3.2 Sensitivity analysis

3.2.1 One-way sensitivity analysis

The outcomes of the OWSA are presented in Fig. 3. Among all the parameters, the discount rate, the cost of tremelimumab, and the cost of durvalumab emerged as the primary

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Table 3. Model parameters and distribution.

Parameter	Baseline value	Lower limit	Upper limit	Distribution	Source
Drug costs (USD)					
Durvalumab (500 mg)	7412.7	5930.16	7412.7	Gamma	https://www.yaozh.com/
Tremelimumab (300 mg)	39000	31200	46800	Gamma	[15]
Sorafenib (200 mg)	1366.34	1093.07	1639.61	Gamma	https://www.yaozh.com/
Optimal supportive care (USD)	265.08	212.06	318.1	Gamma	[16]
Drug administration costs (USD)	35.5	28.4	42.6	Gamma	[16]
Laboratory test costs (USD)	57.46	45.97	68.95	Gamma	[16]
Enhanced CT costs (USD)	95.76	76.61	114.91	Gamma	[16]
Terminal care costs (USD)	2132.67	1706.14	2559.2	Gamma	[16]
Adverse event management costs (USD)					
Diarrhea	28.72	22.98	34.46	Gamma	[16]
Aspartate aminotransferase elevation	122.64	98.11	147.17	Gamma	[16]
Hand-foot skin reaction	42.15	33.72	50.58	Gamma	[16]
Hypertension	18.01	14.41	21.61	Gamma	[16]
Utility values					
PFS state	0.76	0.61	0.91	Beta	[14]
PD state	0.68	0.54	0.82	Beta	[14]
Discount rate	5%	0%	8%	Beta	[16]

Table 4. Results of the basic analysis.

Group	Total cost (USD)	incremental cost (USD)	Utility (QALY)	Incremental utility (QALY)	ICER (USD/QALY)
STRIDE	152729.04	5322.28	1.96	0.48	11027.79
Sorafenib	147406.75	—	1.48	—	—

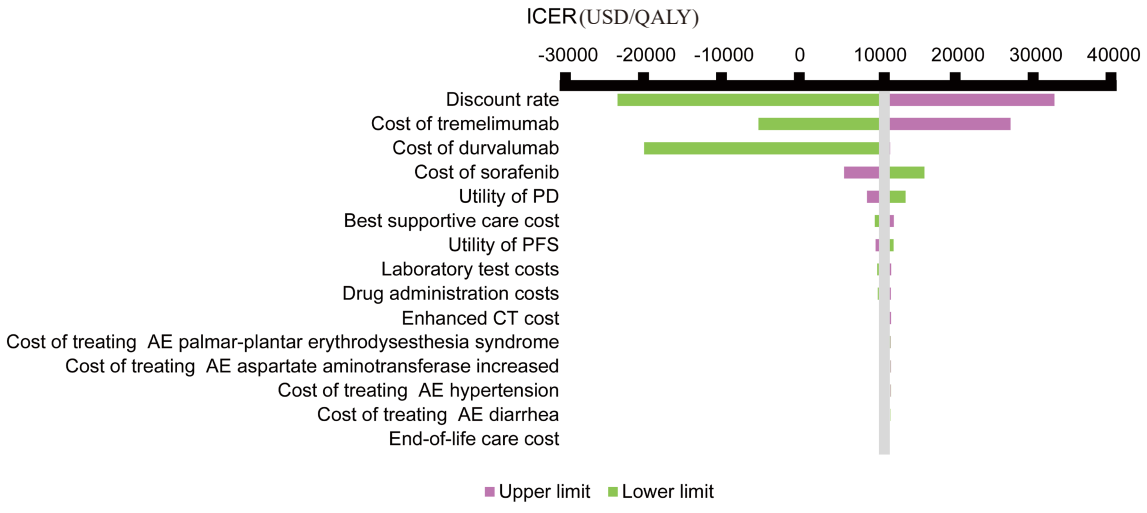

Fig. 3. Single-factor sensitivity analysis whirlwind diagram.

determinants influencing the results. The cost of sorafenib and its utility in the progressive disease state were subsequently identified as secondary factors. In contrast, the impact of other parameters on the results was relatively restricted. Notably, regardless of how the parameters were varied, the ICER did not exceed the WTP threshold. This strongly validates the robustness of the base-case findings.

3.2.2 Probabilistic sensitivity analysis

The cost–effectiveness scatter plot is depicted in Fig. 4. Following 1,000 Monte Carlo simulations, a total of 784 ICER data points were found to be below the WTP threshold. Given that the WTP threshold is set at three times China's 2023 per capita GDP, which amounts to 36,622.13 USD, the likelihood of durvalumab in combination with tremelimumab being cost-effective was calculated to be 78.4%.

Fig. 5 shows the cost–effectiveness acceptability curve. As the WTP threshold increased, the probability of the durvalumab–tremelimumab combination being cost effective also increased. When the WTP threshold was 13,666.38 USD

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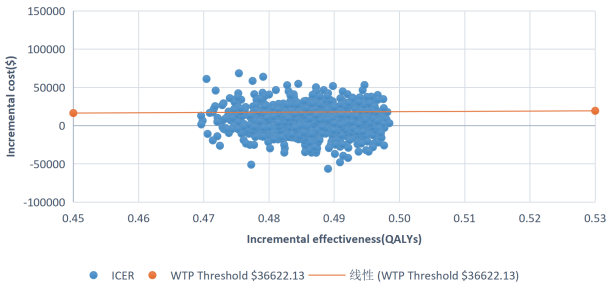

Fig. 4. Cost–effectiveness scatter plot.

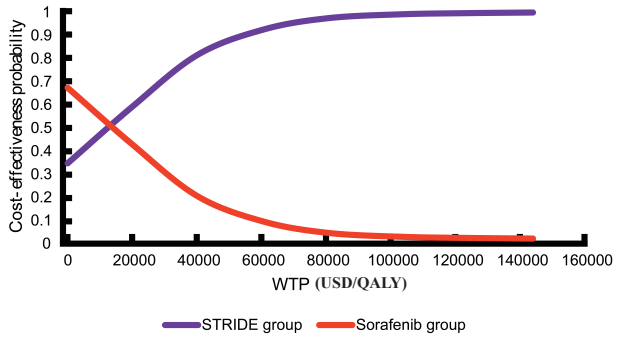

Fig. 5. Cost–effectiveness acceptable curve.

per QALY, this probability stood at 50%. At the WTP threshold of three times China's 2023 per capita GDP (36,622.13 USD/QALY), the probability reached 78.4%. Once the WTP threshold climbed to 144,045.29 USD/QALY, the probability of the combination being cost-effective reached 100%.

4 Discussion

Recently, immune checkpoint inhibitors have demonstrated remarkable efficacy in the treatment of HCC. They have notably increased the survival rate and quality of life of patients. The phase III HIMALAYA trial revealed that, in comparison with sorafenib, the combination of durvalumab and tremelimumab significantly prolonged the mOS in patients with uHCC, with values of 16.43 months versus 13.77 months, respectively[9]. The STRIDE treatment, recommended by the "CSCO Primary Liver Cancer Diagnosis and Treatment Guidelines" for the first-line treatment of uHCC, has been approved by the FDA, the European Union, and Japan for treating uHCC[17]. Nevertheless, in China, STRIDE treatment has not yet been approved for the first-line treatment of uHCC.

This research represents the initial attempt to assess the cost–effectiveness of durvalumab combined with tremelimumab as a first-line treatment for uHCC from the perspective of China's healthcare system. It employs the PS model[18]. The findings indicate that the ICER for the combination of durvalumab and tremelimumab, compared with that of sorafenib, is 11,027.79 USD per QALY. This value is lower than three times China's per capita GDP in 2023, suggesting that the combined treatment is cost-effective. The results of the OWSA show that the discount rate, the cost of tremelimumab, and the cost of durvalumab have a substantial effect on the ICER. The PSA results indicate that when the WTP threshold is set at three times China's 2023 per capita GDP (36,622.13 USD), the probability of the combination of durvalumab and tremelimumab being cost effective is 78.4%. The high cost of tremelimumab significantly influences the cost–effectiveness of the STRIDE regimen. Since tremelimumab has not been approved for marketing in China, its price is sourced from the literature. It is expected that its approval and inclusion in China's medical insurance system will significantly increase the cost–effectiveness of the STRIDE regimen.

Liao et al.[18] evaluated the cost–effectiveness of durvalumab combined with tremelimumab compared with that of sorafenib as a first-line treatment for uHCC from the perspective of U.S. payers via the Markov model. The results showed that, compared with sorafenib, STRIDE treatment extended patients' lives by 0.29 QALYs, while the total cost was lower than that of sorafenib (188,405 USD vs. 218,584 USD). Thus, durvalumab combined with tremelimumab exhibited superior results in both cost and health outcomes, rendering it more cost-effective. Our study is the first to evaluate the STRIDE regimen from the perspective of China's healthcare system, which differs from the perspective of Liao et al. Moreover, unlike the Markov model used in the previous study, this study utilized the PS model. The PS model directly infers the distribution of patients across different states from survival curves. This approach bypasses the calculation of transition probabilities and reduces model assumptions, enabling a better reflection of the actual disease progression and the cost–effectiveness of interventions. This study calculates the cost of second-line treatment on the basis of the proportion of second-line drug use disclosed in the HIMALAYA trial, covering a comprehensive range of drugs. This method better demonstrates the diversity of drug usage in real-world practice. The cost data in this study are sourced from China's databases or referenced from data in China, ensuring high applicability and consistency with the actual situation in China. Atezolizumab combined with bevacizumab, as a first-line treatment for uHCC, has also been evaluated for cost–effectiveness in previous studies. Liu et al.[19] compared the cost–effectiveness of atezolizumab combined with bevacizumab versus sorafenib as first-line treatments for uHCC from the perspectives of China's healthcare system and U.S. payers. The results showed that sorafenib was more cost-effective at thresholds of 31,499 USD/QALY and 150,000 USD/QALY. These findings underscore the significance of the cost–effectiveness of the STRIDE regimen compared with sorafenib as a first-line treatment for uHCC. If the STRIDE regimen is approved in China for first-line treatment of uHCC in the future, it will expand the treatment options for Chinese uHCC patients and benefit more individuals.

This study has certain limitations. First, owing to the absence of utility values specific to Chinese uHCC patients, the utility values used in this study are drawn from relevant literature, which may introduce some biases. It is hoped that future research will concentrate on the utility value preferences of Chinese uHCC patients to further validate the results. Second, only the most common grade 3–4 adverse events were included, and not all adverse events were taken into account, which may deviate from the real-world scenario. However, the cost of managing adverse events is unlikely to reverse the results.

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In summary, from the perspective of China's healthcare framework, durvalumab combined with tremelimumab is more cost-effective as a first-line treatment for uHCC than sorafenib is.

Supporting information

The supporting information for this article can be found online at https://doi.org/10.52396/JUSTC-2025-0035.

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Conflict of interest

The authors declare that they have no conflict of interest.

Biographies

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