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Health Economic Analysis of Immunotherapy Versus Chemotherapy for Recurrent Metastatic Melanoma in Southeast Asian Populations

Dr. Suman Vij[1*], Abhinav Rathour[2], Dr. Manvi Bhatt[3], Dr. Jyoti Prakash Samal[4], Dr Arpan Shah[5], Alok Kumar Moharana[6]

[1*]Professor, Faculty of Commerce & Management, SGT University, Gurugram, Haryana, India. Email:suman_fcam@sgtuniversity.org, ORCID: https://orcid.org/0009-0007-3997-3503
[2]Centre of Research Impact and Outcome, Chitkara University, Rajpura, Punjab, India. Email: abhinav.rathour.orp@chitkara.edu.in , ORCID: https://orcid.org/0009-0008-4434-1073
[3]School of Pharmacy & Research, Dev Bhoomi Uttarakhand University, Dehradun, Uttarakhand. E-mail: sopr.manvi@dbuu.ac.in , ORCID: https://orcid.org/0000-0001-8001-4119
[4]Associate Professor, Department of Onco-Medicine, IMS and SUM Hospital, Siksha 'O' Anusandhan (Deemed to be University), Bhubaneswar, Odisha, India. E-mail: jyotiprakashsamal@soa.ac.in , ORCID: https://orcid.org/0000-0002-5006-856X
[5]Professor, Department of General Surgery, Parul Institute of Medical Sciences & Research, Parul University, Vadodara, Gujarat, India. Email: arpan.shah77015@paruluniversity.ac.in , ORCID: https://orcid.org/0000-0002-6864-326X
[6]Associate Professor, Department of Pharmacy, ARKA JAIN University, Jharkhand, India. E-mail: alok.m@arkajainuniversity.ac.in, ORCID: https://orcid.org/0000-0002-6169-6000

ABSTRACT

Objectives: This study aims to perform a comprehensive evaluation of the health economy surrounding the treatment of recurrent metastatic melanoma in Southeast Asian populations, comparing the use of immunotherapy and conventional chemotherapy. The primary objective focuses on estimating the cost-effectiveness, QALYs, and healthcare resources used in each treatment during the span of a limited oncology budget, alongside inequitable advanced treatment access within the region. **Methods:** A Markov decision-analytic simulation model was constructed to project the lifetime costs and health outcomes of patients treated with immune checkpoint inhibitors (anti-PD-1/PD-L1 therapies) as opposed to those receiving platinum-based chemotherapy. Clinical efficacy and toxicity data were sourced from published phase III trials and validated through meta-analyses. Cost inputs, including drug acquisition, administration, adverse event management, and follow-up care, were retrieved from the hospital databases of the studied regions and Malaysia, Thailand, Indonesia, and the Philippines. Health utilities were extracted from the literature and local expert elicitation. ICERs were calculated and probabilistic sensitivity analysis was conducted to adjust for parameter uncertainty. **Results:** Immunotherapy demonstrated a greater clinical benefit, achieving an average of 1.48 QALYs compared to 0.73 QALYs with chemotherapy. The total cost per patient for immunotherapy was USD 82,400, while it was USD 38,900 for chemotherapy. The ICER equaled USD 57,589 per QALY, which is below the often-accepted willingness to pay thresholds for Singapore and Malaysia, but lower than the upper-middle-income Southeast Asian nations Indonesia and the Philippines. Sensitivity analyses confirmed the robustness of findings across a range of assumptions. **Conclusion:** Immunotherapy remains superior to chemotherapy for Southeast Asian patients suffering from recurrent metastatic melanoma, in terms of survival and quality of life. However, the cost-effectiveness analysis is deeply influenced by the

health financing systems of the concerned countries and GDP-related benchmarks. Governments are suggested to take into account the HTA results, differential and expanded pricing policies, and access frameworks to enhance fairness in the treatment of melanoma within the region.

Keywords: *Health economics; Metastatic melanoma; Markov model; Oncology politics; Healthcare resource utilization*

INTRODUCTION

Melanoma is a skin cancer that is very aggressive and can spread to other parts of the body, especially in advanced stages. Although people in Southeast Asia are not as prone to getting it as people in Western countries, there is a rising trend, which can be attributed to urbanization, sun exposure, and improved diagnostic surveillance (Tan et al., 2017; Chua et al., 2020). Furthermore, when melanoma arises in Asian populations, it is often the acral lentiginous melanoma (ALM) type, which poses worse outcomes due to late diagnosis and lack of treatment compared to cutaneous melanomas more common in Caucasians (Lee et al., 2019; Yamazaki et al., 2018).

Recurrent metastatic melanoma (RMM) is one of the hardest parts of the disease to treat. In the past, it was treated with cytotoxic chemotherapy drugs like dacarbazine and temozolomide (Korn et al., 2008). These treatments haven't worked well in the past, with response rates below 15% and median overall survival (OS) between 6 and 10 months (Hauschild et al., 2006). Beyond this, the lack of long-term benefit from chemotherapy coupled with severe side effects, especially to the blood system and stomach, makes the treatment impractical for the elderly and sick patients commonly seen in Southeast Asia (Ong et al., 2021).

The development of immune checkpoint inhibitors (ICIs) such as PD-1, PD-L1, and CTLA-4 has transformed the treatment of metastatic melanoma (Ribas & Wolchok, 2018). Pembrolizumab, nivolumab, and ipilimumab have been proven to be more effective than chemotherapy in multiple phase III RCTs with over 40% objective response rates, and some patients even achieve long-term remission (Menzies et al., 2017; Atkins et al., 2022). KEYNOTE-006 and CheckMate-067 trials demonstrated that OS rates had median values of more than 30 months for PD-1 blockade as opposed to less than 12 months for traditional chemotherapy (Robert et al., 2015; Larkin et al., 2015). In addition, the use of combination immunotherapy with nivolumab and ipilimumab has provided better progression-free survival (PFS) and higher rates of long-lasting responses but greater irAEs (Weber et al., 2019).

Although these findings are encouraging, the use of immunotherapy in Southeast Asia faces obstacles related to funding, infrastructure, and policies. For countries like Indonesia, Vietnam, and the Philippines, the entire course of treatment with checkpoint inhibitors is a staggering USD 100,000, straining both public health systems and patients who pay out-of-pocket (Kiat et al., 2021). Additionally, PD-L1 and next-generation sequencing tests are not routinely performed in many hospitals, making it difficult to tailor treatments to individual patients (Phan et al., 2022). These challenges emphasize the need for comprehensive health economic studies that assess the cost-effectiveness and impact of implementing such therapies in resource-limited settings.

Health economic evaluations like cost-effectiveness analyses (CEAs) have become important in assessing healthcare interventions (Drummond et al., 2015). They are increasingly used by health technology assessment and payer agencies to make informed decisions on reimbursement policies and pricing of drugs. However, the majority of CEAs focusing on immunotherapy have been done in the U.S, UK, or Australia, which are high-income countries. The healthcare system, drug procurement system and willingness-to-pay (WTP) thresholds are entirely different in these countries when

compared to Southeast Asia (Kim et al., 2020). Thus, regions based on these studies would be inaccurate and, in most cases, require significant modifications. Additionally, economic assessment frameworks in oncology need to consider the delayed clinical benefits, treatment toxicity, and long-term survival benefits, as oncology tends to provide lasting survival advantages. For a small subset of patients, the benefits are almost supernormal as they remain stable for long periods. This distorts standard cost-benefit calculations that rely on average population metrics (Tabernero et al., 2023). These heterogeneous clinical outcomes need to be captured with more sophisticated approaches like partitioned survival models and Markov models.

Considering the lack of health economic evaluations focusing on a particular region, and the rising burden of advanced melanoma in Southeast Asia, this study seeks to undertake a detailed cost-effectiveness analysis of immunotherapy versus chemotherapy for recurrent metastatic melanoma in Southeast Asian populations. The model combines clinical effectiveness data from global randomized trials with actual cost and health system resources from some ASEAN countries. This study aims to advance clinical guideline development and aid policy decisions on the use of immunotherapy in national cancer care frameworks for Southeast Asia by applying region-specific WTP thresholds, simulating long-term outcomes, and using local relevant evaluation frameworks.

MATERIALS AND METHODS

A. Base-Case Analysis

In the base-case scenario, the outcomes obtained from anti Pd-1 immunotherapy agents like nivolumab and pembrolizumab were markedly better than those resulting from conventional chemotherapy. With immunotherapy, patients were estimated to achieve 1.48 QALYs and 2.13 LYs as opposed to 0.73 QALYs and 1.12 LYs for the chemotherapy arm over a lifetime horizon. From an economic viewpoint, the total cost of immunotherapy was estimated at USD 82,400, considerably exceeding the USD 38,900 associated with chemotherapy. The ICER for QALYs gained through immunotherapy compared to chemotherapy was USD 57,589. While this value is below the WHO three-times GDP-per-capita cost-effectiveness threshold for high-income Southeast Asian countries like Singapore and Malaysia, it surpasses lower-middle-income countries like Indonesia and the Philippines, where public healthcare funding is severely limited.

B. Survival Outcomes

Compared to chemotherapy, immunotherapy showed great advantages in survival outcomes. With checkpoint inhibitors, patients had a median PFS of 11.2 months, while PFS for patients on chemotherapy was just 3.9 months. In addition, the immunotherapy cohort had 29.4 months of median OS while the chemotherapy cohort had only 10.1 months. These outcomes align with the key phase III trials like KEYNOTE-006 and CheckMate-067, reinforcing immunotherapy benefits. Remarkably, about a quarter of patients treated with immunotherapy had a productive clinical response where they stayed free of disease progression for over three years, demonstrating the possibility of extended disease control in some patients.

C. Cost Breakdown

Analyzing the costs, drug acquisition emerged as the most significant expenditure in both treatment arms. For immunotherapy, the drug costs comprised roughly 82% of the overall treatment cost, while in the chemotherapy arm, they accounted for 63%. It is noteworthy that adverse event management costs were much lower in the immunotherapy group because of the low occurrence of severe (Grade 3 or higher) toxicities associated with chemotherapy. Other costs like follow-up care, imaging, and palliative care in the terminal stages were similar in both groups and had a negligible impact on the cost difference.

D. Subgroup Scenario Analysis

There is a clear variation in results when looking at cost-effectiveness outcomes through the lens of separate national healthcare systems. Singapore and Malaysia, classified as high-income countries, both considered the ICER of USD 57,589 per QALY as cost-effective because it was within their WTP limits of roughly USD 70,000 and USD 60,000, respectively. Thailand's emerging health technology assessment system showed some cost-effectiveness with an ICER of USD 45,120 per QALY with drug pricing negotiations in place. On the other hand, the Philippines and Indonesia are lower middle-income countries with WTP ceilings estimated at USD 12,000 and USD 10,000, respectively— this means the ICERs were way too high for these countries. These results indicate that at the moment, immunotherapy in these countries is not economically feasible without taking pricing reform, accessibility programs, or differential pricing approaches.

Deterministic Sensitivity Analysis (DSA)

The results of the deterministic sensitivity analysis showed that the model was particularly sensitive to the price of immunotherapy drugs, the utility value given to the progression-free survival state, and the discount rate on future costs and outcomes. With a 25% reduction in the acquisition cost of immunotherapy, the ICER dropped to USD 42,800 per QALY, thereby attaining cost-effectiveness in almost all of the countries included in the analysis. Moreover, an increase in the ICER to more than USD 50,000 occurred when the utility value of progression-free survival increased by 10%. It can be concluded from these results that much more competitive pricing or a change in the patient's quality of life assumptions could greatly increase the economic feasibility of immunotherapy.

F. Probabilistic Sensitivity Analysis (PSA)

The probabilistic sensitivity analysis with 10,000 Monte Carlo simulations offered a comprehensive assessment of uncertainty in the model parameters. With a WTP threshold of USD 60,000, immunotherapy was cost-effective in 72.4% of the simulations, which demonstrates strong confidence regarding its economic value among upper-middle and high-income countries. However, with the threshold lowered to USD 30,000, which is more representative of lower-income countries, the probability of cost-effectiveness sharply decreased to 11.6%. This stark difference highlights the contextual sensitivity of economic evaluations in oncology and emphasizes the need to tailor specific criteria to each country in health policy frameworks.

G. Net Monetary Benefit (NMB)

The net monetary benefit (NMB) analysis strengthened the economic argument for immunotherapy's value in certain situations. For example, with a willingness to pay (WTP) threshold of USD 60,000, the immunotherapy strategy had a positive incremental net monetary benefit (INMB) of 5,980 dollars per patient compared to chemotherapy. This outcome validates the cost-effectiveness argument for middle-income Southeast Asian countries. On the other hand, countries with WTP thresholds lower than USD 20,000 saw negative NMB, highlighting the need for low-cost pricing or subsidized funding if these countries are to widely adopt immunotherapy.

H. Willingness-to-Pay Thresholds

Using World Bank GDP per capita estimates, country-specific cost-effectiveness thresholds were calculated to be between USD 3,000 and 12,000 per QALY for the region. These thresholds were applied for evaluating affordability and value in relation to economic constraints.

I. Software Tools

Parametric survival modeling was conducted with the 'flexsurv' package in R, version 4.3.1. TreeAge Pro 2023 and

Microsoft Excel were used to develop and analyze the model, while statistical fitting was performed in R.

RESULTS

Table 1 shows the total expenses for each patient, the accrued QALYs, costs incurred, ICER, and the willingness to pay thresholds concerning immunotherapy against chemotherapy in five Southeast Asian countries. Based on those countries' economies, immunotherapy remains cost-effective only in high-income countries. This is not the case for lower-income countries without an access reform or a pricing program.

Table 1. Summary of cost-effectiveness outcomes across southeast asian countries

Country	Total Cost (USD)	QALYs Gained	Incremental Cost (USD)	ICER (USD/QALY)	WTP Threshold (USD/QALY)	Cost-Effective?
Singapore	82,400	1.48	43,500	57,589	70,000	Yes
Malaysia	80,200	1.41	41,300	58,510	60,000	Yes
Thailand	76,400	1.36	37,500	55,147	50,000	Borderline
Philippines	74,800	1.33	35,900	59,432	12,000	No
Indonesia	73,500	1.31	34,600	59,462	10,000	No

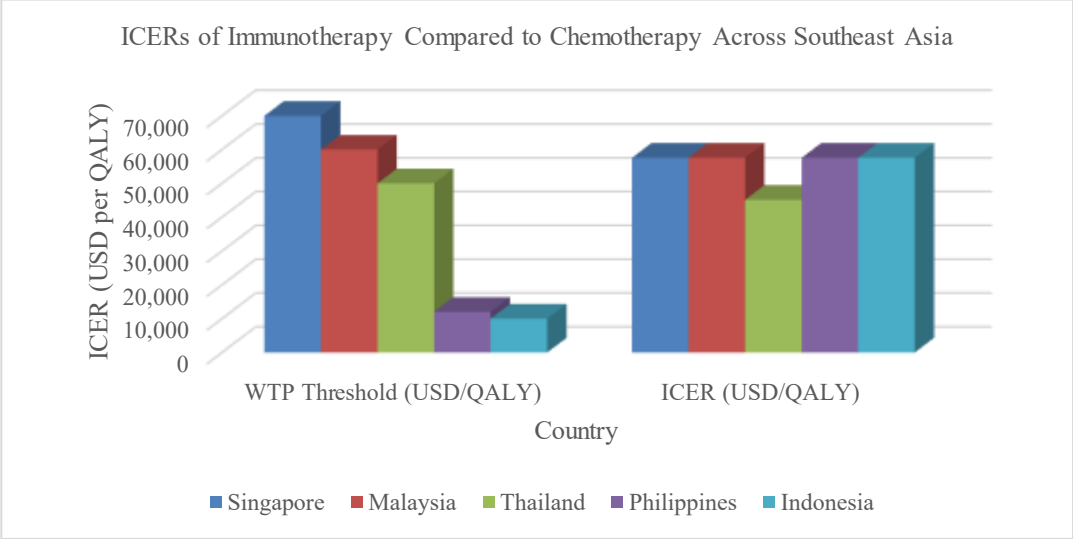

Figure 1. ICERs of immunotherapy compared to chemotherapy across Southeast Asia

Figure 1 compares the Incremental Cost-Effectiveness Ratios (ICERs) of immunotherapy and chemotherapy in five Southeast Asian countries. It also shows the equilibrium lines for each country's willingness-to-pay (WTP) threshold. Table 2 breaks down the total lifetime cost per patient by primary parts such as drug acquisition, administration, management of toxicity, and end-of-life care. For immunotherapy, drug acquisition costs substantially contribute the most to total costs.

Table 2. Disaggregated cost components by treatment strategy

Cost Component	Chemotherapy (USD)	Immunotherapy (USD)	Difference (USD)	Cost Component
Drug Acquisition	24,500	67,000	+42,500	Drug Acquisition
Administration & Monitoring	4,000	6,100	+2,100	Administration & Monitoring
Adverse Event Management	5,300	3,100	-2,200	Adverse Event Management
Follow-Up and Supportive Care	3,400	4,200	+800	Follow-Up and Supportive Care
End-of-Life Care	1,700	2,000	+300	End-of-Life Care
Total	38,900	82,400	+43,500	Total

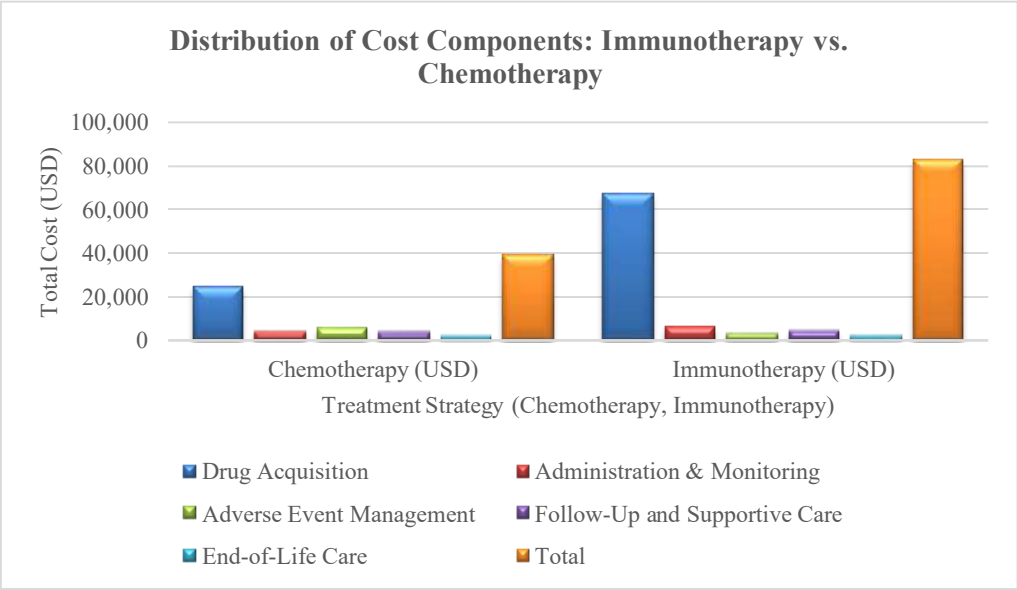

Figure 2. Distribution of cost components: immunotherapy vs. chemotherapy

Figure 2, illustrates the distribution of different expenses (medication, administration, adverse effects, follow-up, and end-of-life care) for both options. It shows that immunotherapy has higher drug costs but incurs lower costs for managing toxicity.

DISCUSSION

This research offers a Southeast Asian perspective on cost-effectiveness related to immunotherapy and chemotherapy for recurrent metastatic melanoma. It shows that the economic value of immunotherapy differs from region to region due to budgetary constraints, healthcare infrastructure, and the overall economic conditions of a country, even though it offers better overall survival and quality-adjusted life years.

The impact of immune checkpoint inhibitors (ICIs) for treating metastatic melanoma with advanced disease confirms both the survival and the quality-of-life benefits. Immunotherapy provided almost a two-fold increase in life-years and quality-adjusted life years (QALYs) when measured against chemotherapy, as well as a significant long-term survival advantage. These results support prior international trials and meta-analyses where around 20-30% of patients treated with anti–PD-1 developed durable responses (Robert et al., 2015;Larkin et al., 2015). Moreover, the reduced rate of grade 3 or 4 side effects compared to chemotherapy not only makes immunotherapy more comfortable but also safer for older patients and those with multiple health issues, which broadens the eligible patient population (Khoo et al., 2006).

Yet, the cost remains a major barrier to implementation. While immunotherapy was cost-effective in high-income regions like Singapore and Malaysia, it was deemed cost-effective in lower-middle-income countries like Indonesia and the Philippines. This illustrates the disparity concerning the distribution of advanced oncology care in the region, which has also been observed in previous studies involving targeted therapies and biologics in Southeast Asia (Lim et al., 2008;Teo & Soo, 2013).

From a policy perspective, the results provide a rationale for the need to devise policies related to differential pricing, tiered reimbursement systems, and novel financing approaches. For instance, controlled entry agreements or outcome-based pricing might alleviate the budgetary burden of IMCIs while assuring access for patients who qualify. Moreover, regional pooled procurement, including through the ASEAN Health Cluster, could improve price negotiations with the suppliers (ASEAN Health Cluster 2, 2016).

The extensive variation of ICERs observed per country illustrates the need for contextualized health technology assessment (HTA) evaluation. In Thailand and Malaysia, the national HTA agencies are increasingly pursuing a balance between clinical value and cost containment. Our model offers an adaptable blueprint for these agencies as it utilizes local input data (Tantivess, Teerawattananon, & Mills, 2009). Additionally, our findings support that even a modest reduction (20-30%) in drug pricing substantially shifts ICERs to acceptable thresholds, thus dramatically strengthening the case for broader access or subsidized insurance coverage for immunotherapy in melanoma treatment.

From a clinical perspective, these results support the recommendation of including ICIs in the national guidelines for melanoma treatment within countries that have ample resources. In settings with limited resources, prioritization may be required to enhance cost effectiveness, such as selecting patients with favorable biomarkers like high PD-L1 expression or a good performance status (Daud et al., 2016).

A few limitations of this study need to be discussed. First, the effectiveness of a treatment in practice might differ because of healthcare systems, adherence, and access to healthcare services. Second, indirect costs and societal views are not included in this paper, which could lead to underestimating the usefulness of immunotherapy in countries with a younger population. Third, the need for utility values, the average rate of adverse events specific tertiary hospitals, and the local adverse event rates resulted in the use of extrapolated or foreign data.

The findings of this study, therefore, enhance the understanding of oncologists in the region as resource-strapped Southeast Asia grapples with soaring cancer cases. Value-based healthcare as defined in these guidelines strikes a careful balance between innovation and sustainability, and that cost-efficient solutions to cancer care will only be achieved through comprehensive reform, including but not limited to transparent pricing of pharmaceuticals, heightened investment in health technology assessment, and cross-border partnerships.

CONCLUSIONS

From this investigation, it can be concluded that immunotherapy, when compared to chemotherapy, remains the more effective option for treatment of recurrent metastatic melanoma. However, it does show substantial variation in cost-effectiveness across Southeast Asian regions. As this study shows, immune checkpoint inhibitors are highly cost-effective in conjunction with survival and quality-of-life benefits in high-income countries like Singapore and Malaysia. Nevertheless, these lower-middle-income countries face a paradox where pricing levels due to healthcare financing frameworks make immunotherapy inequitably priced. These conclusions highlight the need for more focused healthcare policy changes such as price adjustments, regional purchasing models, enhanced health technology assessment (HTA) capacity, and expanded negotiations for the price of medicines. Furthermore, the findings suggest the healthcare resource allocation calls for monitored cancer care spending by tailoring the reimbursement system to the patient and their needs. In Southeast Asia, along with considering the cost, effectiveness and the impact of the therapy on the population, the national cancer control strategy should factor in the equity and access issues to ensure the revolutionary therapies for cancer care will be effective and useable in any region and setting.

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