Cost-effectiveness of olaparib, a PARP inhibitor, for patients with metastatic castration-resistant prostate cancer in China and United States

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Background: Metastatic prostate cancer is initially sensitive to androgen receptor inhibition, but eventually becomes metastatic castration-resistant prostate cancer (mCRPC). Olaparib has longer progression-free survival and better measures of response and patient-reported end points than either enzalutamide or abiraterone. In the present study, 2 Markov models were established to analyze the cost utility of olaparib in treating mCRPC from the perspectives of health services in China and the United States.

Methods: Markov models were established to simulate the progress of mCRPC in China and the United States. The state transition probabilities and clinical data were extracted from the PROfound trial. The cost data were estimated from local pricing, the relevant literature and expert consultancy. The health outcomes are expressed by quality-adjusted life years (QALYs). All costs and incremental cost-effectiveness ratios (ICERs) are presented in US dollars. One-way deterministic sensitivity analysis and probabilistic sensitivity analysis were performed to assess the uncertainty of the models.

Results: Based on the Chinese Markov model, the base case ICER for olaparib versus the control group was ¥392,727.87, with incremental costs of ¥93,673.23 and an incremental QALY of 0.23, indicating that it was not cost effective from the aspect of the Chinese healthcare system. However, as shown by the American Markov model, olaparib was dominant versus the control group, with a cost saving of $69,675.20 and a gain of 0.23 QALYs. One-way deterministic sensitivity analysis and probabilistic sensitivity analyses showed that the modeling results were not significantly affected by the model parameters.

Conclusions: Olaparib treatment in patients with mCRPC is not cost effective in China, but it is cost saving in the United States.

Keywords: Olaparib; metastatic castration-resistant prostate cancer; Markov model

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Introduction

Prostate cancer is a common malignant tumor of the male genitourinary system (1). Based on global cancer statistics, in 2020, the incidence of prostate cancer ranked second among malignancies in males worldwide, and its mortality rate ranked fifth (2). The incidence and mortality of prostate cancer vary by race and region. In 2019, the new incidence of prostate cancer ranked first among malignant tumors in males in the United States, and its mortality ranked second (3), as reported by the American Cancer Society. In China, prostate cancer has overtaken bladder cancer as the prevalent malignant tumor of the urinary system (4). The primary treatment for advanced prostate cancer is androgen deprivation therapy, which often achieves a satisfactory effect at the early stage. However, after approximately 18–24 months of remission, nearly all cases may develop castration-resistant prostate cancer (CRPC), which is the most frequent cause of death among patients with prostate cancer and is a challenge in the treatment of prostate cancer (5).

Olaparib is the world's first oral poly(adenosine diphosphate-ribose) polymerase (PARP) inhibitor. It is used to inhibit DNA repair and has been approved as the first-line maintenance treatment of platinum-sensitive recurrent epithelial ovarian cancer, carcinoma tube or primary peritoneal carcinoma, and BRCA-mutated advanced ovarian cancer. The results of olaparib treatment obtained from the PROfound trial are as follows: olaparib extends the radiographic progression-free survival (rPFS) of patients with mCRPC two times with BRCA1/2 or ATM mutation and reduces the disease progression or risk of death of HRR-mutated patients by 51% (6). Therefore, in May 2020, olaparib was approved as a treatment for mCRPC by the United States Food and Drug Administration (FDA), and it was available as the preferred therapeutic regimen for mCRPC in patients with BRCA1/2, ATM, or HRR mutation (7). In June 2021, olaparib was also approved by the National Medical Products Administration of the People's Republic of China for single-dose treatment of adults with germline or somatic BRCA mutation (gBRCAm or sBRCAm) and with failed prior treatment (including a new endocrine drug) of mCRPC, as well as for the effective treatment of patients with advanced endocrine-resistant refractory prostate cancer. However, olaparib is expensive, often posing a heavy economic burden on patients and their families. In addition, neither evidence on whether olaparib is cost effective for the treatment of mCRPC nor a scientific verdict on its cost is available at present. A cost-effectiveness analysis compares the cost and effectiveness per unit of a given program to determine whether the value of an intervention justifies its cost. It provides the metrics to rank or compare similar interventions or projects that result in the same effect. By establishing a Markov model, the cost-utility scores of olaparib in the treatment of mCRPC in China and the United States were analyzed in the present study, thereby providing an economic basis for the decision-making of doctors, patients' clinical medications, and government departments' healthcare decision-making in China and the United States. We present the following article in accordance with the CHEERS reporting checklist (available at https://atm.amegroups.com/article/view/10.21037/atm-22-3637/rc).

Methods

Subjects and methods

All data in the present study were obtained from the PROfound trial (6), a prospective, multi-center, randomized, and open-label phase III trial. The inclusion criteria were as follows: (I) male patients diagnosed with mCRPC, no less than 18 years old; (II) patients with BRCA 1/2 or ATM mutation; (III) patients with worsened conditions during mCRPC treatment, non-mCRPC, or metastatic hormone-sensitive prostate cancer treated with enzalutamide or abiraterone; (IV) patients who had received taxane-based chemotherapy; (V) patients who had never received surgical castration but had continued treatment with luteinizing hormone-releasing analogues; and (VI) patients with their organs, bone marrow, and other functional indicators good enough to support the subsequent treatment. The therapeutic regimen during progression-free survival (PFS) was determined by the PROfound trial, whereas that during the disease progression was in line with the National Comprehensive Cancer Network (NCCN) Prostate Cancer Guidelines (2020), China's Guidelines on the Comprehensive Diagnosis and Treatment of Prostate Cancer, and clinical trials related to all data sources of the present study. The total dosing regimen involved was as follows: (I) for the group treated with olaparib, the dosing regimen was olaparib 300 mg orally 2 times a day. The treatment continued until the disease progressed or until the criteria for dropouts were met. After disease progression, treatment with docetaxel continued, and the dosing regimen was docetaxel 375 mg/m^2 infusion every 3 weeks, 1 h once, combined with prednisone 5 mg, 2 times

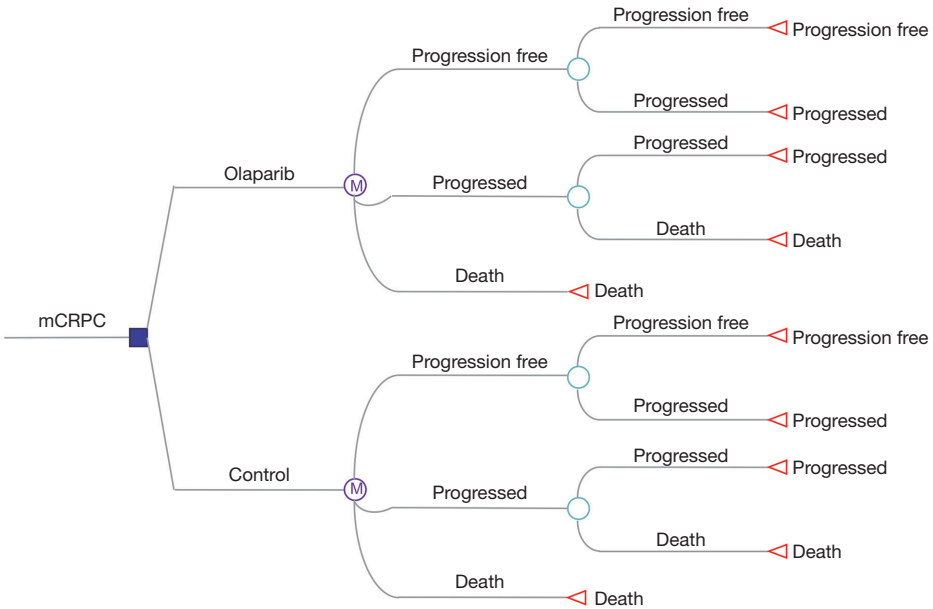

Figure 1 Markov model structure diagram. mCRPC, metastatic castration-resistant prostate cancer.

a day (8); (II) for the control group, the dosing regimen was oral enzalutamide (160 mg, once a day) or abiraterone acetate (1,000 mg, once a day, combined with prednisone 5 mg, 2 times a day). The treatment continued until the disease progressed or until the criteria for dropouts were met. The treatment with the regimen continued after disease progression, optionally combined with enzalutamide or abiraterone acetate.

Model establishment

In the present study, the Markov model was adopted to simulate disease progression. Two scenarios were designed from the perspectives of the health service systems in China and the United States. Based on the relevant data obtained from the PROfound trial, the model was divided into 3 mutually independent states: PFS, progressed disease (PD), and death. The Weibull distribution was applied. The PFS and overall survival (OS) curves were fitted on the basis of the relevant data from the PROfound trial. The shape and scale parameters of the Weibull distribution function were calculated and placed into the transition probability formula. Thus, the transition probability *T*p that varied with time at different stages was obtained using TreeAge software. In the formula, "t" and "u" represent the time and period during which the Markov model runs, respectively.

$$Tp = 1 - \exp\left(-scale \times (t+u)^{shape} - scale \times t^{shape}\right) \quad [1]$$

According to the Markov state, a Markov model tree was established using TreeAge, and the Markov models in China and the United States were set as follows: the cycle was set to 1 month (i.e., 30 days), and the time horizon was set to 5 years (61 cycles). When the model was terminated, most patients in the model reached an absorbing state (*Figure 1*).

Statistical analysis

Costs and utilities

Costs of the present study covered fees for drugs, injections, examinations, nursing, routine follow-up, and adverse reaction treatment (9-15). Costs involved in the modeling were on a cycle basis and discounted until 2021. In our study, the cost of the United States Markov model was in US dollars, whereas that of the Chinese Markov model was in RMB. The health utility values were measured by quality-adjusted life years (QALYs). The health utility values of different states were obtained from published articles on pharmacoeconomics (8,16,17), with specific values given in *Tables 1-3*. Both costs and utilities were discounted, and the discount rate referred to in the Chinese Markov models was 5% (0–8%) based on the China Guidelines for Pharmacoeconomic Evaluations (2019), whereas that in the United States Markov model was 3% (0–7%) based on the

Table 1 Costs in the United States

Parameter name	Base ($)	Range ($)	Distribution	Source(s)
Medication costs				
PFS				
Olaparib (150 mg)	115.72	61.13–125.78	–	Redbook, drugs.com
Olaparib (per cycle)	14,731.66	7,335.60–15,094.14	–	Redbook, drugs.com
Enzalutamide (40 mg)	115.486	92.389–138.583	Gamma	(8)
Enzalutamide (per cycle)	13,858.32	11,086.68–16,629.96	Gamma	(8)
Abiraterone (250 mg)	95.26	76.208–114.312	Gamma	(8)
Abiraterone (per cycle)	11,431.2	9,144.96–13,717.44	Gamma	(8)
Prednisone (per cycle)	23.4	18.72–28.08	Gamma	(8)
PD				
Docetaxel (per cycle)	2,228.95	375.56–2,418.85	Gamma	(16)
Prednisone (per cycle)	23.4	18.72–28.08	Gamma	(8)
Non-pharmaceutical cost				
Laboratory testing (per cycle)	12.67	11.33–14.00	Gamma	(8)
CT (per cycle)	828.00	598.00–1,083.00	Gamma	(8)
PSA (per cycle)	25	20–30	Gamma	(8)
Bone imaging (per cycle)	253.46	202.77–304.15	Gamma	(8)
Nursing fee (per cycle)	1,617	1,316–1,917	Gamma	(8)
Routine follow-up (per cycle)	422	348.10–495.80	Gamma	(8)
Cost of treatment of adverse reactions				
Anemia	1,134.10	1,020.59–1,247.62	Gamma	(9)
Nausea	719.54	465.65–1,027.80	–	(10)
Fatigue	9,857.88	9,168.30–1,0547.47	Gamma	(9)
Vomiting	719.54	465.65–1,027.80	–	(10)
Back pain	12,534.53	11,280.55–13,787.46	Gamma	(9)
Urinary tract infection	8,664.46	5,079.38–16,051.08	–	(11)

PFS, progression-free survival; PD, progressed disease; CT, computed tomography; PSA, prostate specific antigen.

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Cost-effectiveness analysis

The findings of the present study cover costs, QALYs, and incremental cost-effectiveness ratio (ICER). All findings of ICERs were compared with the willingness-to-pay (WTP) threshold, and the investigated object was more cost effective than the control group when the ICER was less than the WTP and vice versa. Based on the China Guidelines for Pharmacoeconomic Evaluations, the threshold (i.e., WTP) is usually set to 3 times the GDP (18). In 2020, China's GDP per capita found on the website of the National Bureau of Statistics was ¥72,447, thereby obtaining an annual WTP of ¥217,341, and the WTP in the United States model was set to $150,000 based on the related literature (19).

Sensitivity analysis

One-way deterministic sensitivity analysis and probabilistic sensitivity analysis were performed on the model parameters to evaluate its stability, and one-way deterministic sensitivity

Table 2 Costs in China

Parameter name	Base (RMB)	Range (RMB)	Distribution	Source
Medication costs				
PFS				
Olaparib (150 mg)	102.00	51.00–442.68	–	www.yaozh.com
Olaparib (per cycle)	12,240.00	12,240.00–53,121.43	–	www.yaozh.com
Enzalutamide (40 mg)	69.60	69.60–321.43	–	www.yaozh.com
Enzalutamide (per cycle)	8,352.00	8,352.00–38,571.43	–	www.yaozh.com
Abiraterone (250 mg)	35.80	23.33–108.46	–	www.yaozh.com
Abiraterone (per cycle)	4,296.00	2,800.00–13,015.20	–	www.yaozh.com
Prednisone (per cycle)	3.78	2.16–7.17	–	www.yaozh.com
PD				
Docetaxel (0.5 mL: 20 mg)	808.00	65.20–1207.48	–	www.yaozh.com
Docetaxel (per cycle)	6,464.00	1,564.80–28,979.52	–	www.yaozh.com
Prednisone (per cycle)	3.78	2.16–7.17	–	www.yaozh.com
Non-pharmaceutical cost				
Laboratory testing (cycle)	551.25	529.20–573.30	Gamma	(12)
CT (per cycle)	345	230–860	–	Tertiary hospitals
PSA (per cycle)	38	20–68	–	Tertiary hospitals
Bone imaging (per cycle)	260	200–350	–	Tertiary hospitals
Nursing fee (per cycle)	1,350	900–2,400	–	Tertiary hospitals
Routine follow-up (per cycle)	51.5	41.2–61.8	Gamma	(13)
General ward (per day)	65	30–150	–	Tertiary hospitals
General ward (per cycle)	1,950	900–4,500	–	Tertiary hospitals
Cost of treatment of adverse reactions				
Anemia	3,893.05	2,920.17–4,866.70	Gamma	(14)
Nausea	467.49	421.28–514.20	Gamma	(15)
Fatigue	595.84	540.71–650.96	Gamma	(12)
Vomiting	467.49	421.28–514.20	Gamma	(15)
Back pain	81.14	26.02–136.27	Gamma	(12)
Urinary tract infection	221.20	55.30–442.40	–	Expert consultancy

PFS, progression-free survival; PD, progressed disease; CT, computed tomography; PSA, prostate specific antigen.

analysis results were shown in a tornado diagram. In the probabilistic sensitivity analysis, by extracting the values of different variables from the corresponding distributions, a Monte Carlo simulation was performed 1,000 times for between-group comparison, and the results were shown in an ICER scatter plot and cost-utility acceptability curve.

Results

Basic results

From the perspective of the Chinese health services, the results showed that the cost of treating Chinese mCRPC patients with olaparib was ¥287,011.03, with utility of 0.96

Table 3 Health utility value

Parameter name	Base	Range for sensitivity analysis	Distribution	Source
PFS	0.617	0.494–0.74	Beta	(8)
PD	0.37	0.296–0.444	Beta	(8)
Anemia	–0.119	–	–	(16)
Nausea	–0.21	–0.25–0.17	–	(17)
Fatigue	–0.09	–0.12–0.05	–	(17)
Vomiting	–0.21	–0.25–0.17	–	(17)
Back pain	–0.067	–	–	(16)
Urinary tract infection	–0.07	–0.10–0.04	–	(17)

PFS, progression-free survival; PD, progressed disease.

Table 4 The results of cost-effectiveness analysis (China)

Regimen	Cost (¥)	Utility (QALY gain)	Incremental cost (¥)	The incremental utility (QALY gain)	Incremental cost-utility ratio (¥/QALY gain)
Olaparib	287,011.03	0.96	93,673.23	0.23	392,727.87
The control group	193,337.81	0.73	–	–	–

QALY, quality-adjusted life years.

Table 5 The results of cost-effectiveness analysis (US)

Regimen	Cost ($)	Utility (QALY gain)	Incremental cost ($)	The incremental utility (QALY gain)	Incremental cost-utility ratio ($/QALY)
Olaparib	240,932.18	0.96	–	–	–
The control group	310,607.38	0.73	69,675.20	–0.23	–302,935.65

QALY, quality-adjusted life years.

QALYs, whereas that of the control group was ¥193,337.81, with utility of 0.73 QALYs. In addition, the ICER was ¥392,727.87/QALY (*Table 4*), which was greater than the WTP in China (¥217,341/QALY). This result indicated that olaparib treatment is not cost effective in Chinese patients with mCRPC.

From the perspective of the United States health services, the results showed that the cost of olaparib treatment in patients with mCRPC was $240,932.18, with 0.96 QALYs, whereas that of the control group was $310,607.38, with 0.73 QALYs (*Table 5*). Evidently, the group treated with olaparib obtained a higher utility at a lower cost, that is, the option to treat mCRPC patients with olaparib was cost effective in the United States.

Sensitivity analysis

One-way deterministic sensitivity analysis

One-way deterministic sensitivity analysis was performed on the Chinese Markov model (*Figure 2A*). The tornado diagram showed that the top 5 factors associated with the findings of the model were the price of docetaxel, olaparib, enzalutamide, and abiraterone, and the utility score at PFS, whereas those associated with the findings of the United States Markov model were the price of olaparib, enzalutamide, docetaxel, and abiraterone, and the utility score at PFS (*Figure 2B*).

Probabilistic sensitivity analysis

The Monte Carlo simulation results showed that in the

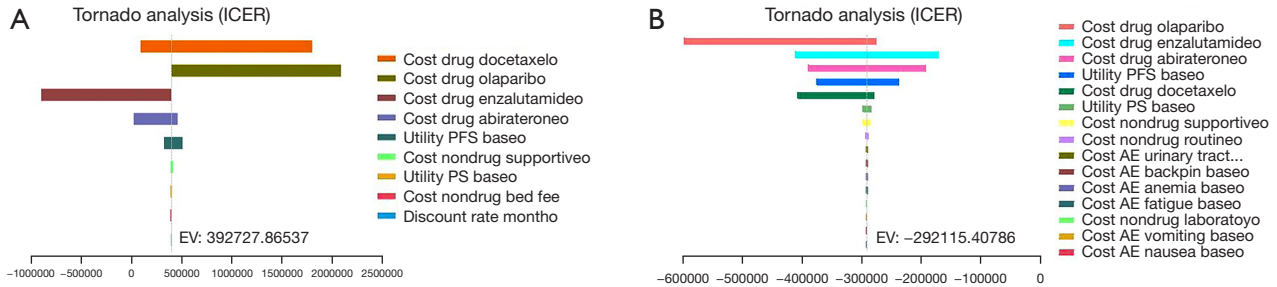

Figure 2 Tornado diagram of single factor sensitivity analysis of the Markov model.

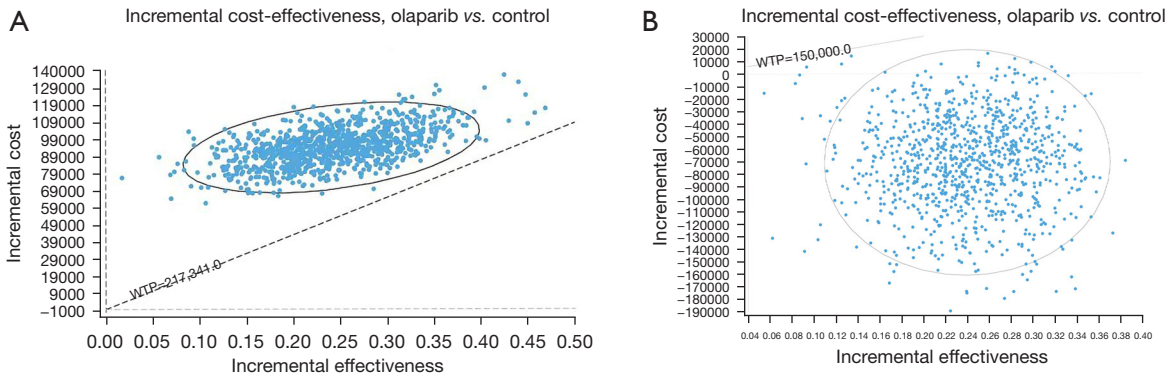

Figure 3 The cost-effectiveness scatter plot of the Markov model.

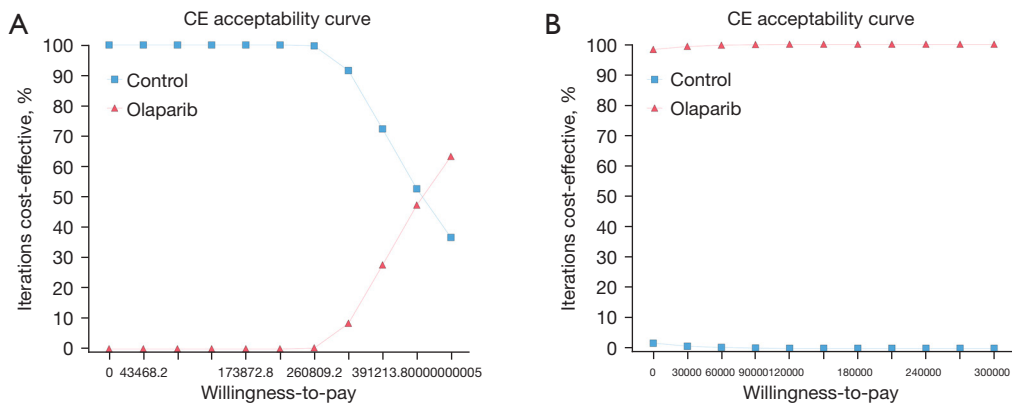

Figure 4 The acceptability curve of the Markov model in China (A) and in the United States (B). CE , cost effectiveness.

Chinese Markov model, more than 95% of the points fell above the WTP threshold curve, indicating that it is not cost effective to treat Chinese mCRPC patients with olaparib (*Figure 3A*). In contrast, in the United States Markov model, more than 95% of the points fell below the WTP threshold curve, and almost no points fell above it, indicating that it is cost-effective to treat mCRPC patients in the United States with olaparib (*Figure 3B*). Cost acceptance curve results showed higher patient acceptance as China's WTP threshold increased (*Figure 4*).

Discussion

By inhibiting DNA repair, olaparib has a double inhibitory

effect on DNA repair-defective tumor cells with BRCA mutation and an effective inhibitory effect on tumor cells in BRCA-mutated patients as revealed by fundamental studies and clinical trials (20). Olaparib is available for patients with BRCA1/2-mutated mCRPC. However, given its high price, the long-term use of olaparib could dramatically increase medical expenses. Therefore, evaluating the cost-utility scores of olaparib from the perspective of pharmacoeconomics is of great significance, though there are few studies on the cost-utility scores of olaparib in treating mCRPC. From the perspective of United States payers, Li *et al.* (21) evaluated the cost-utility scores of olaparib in treating mCRPC patients with BRCA1, BRCA2, or ATM mutation, and the results showed that the cost and utility of olaparib treatment were $157,732 and 1.26 QALYs, respectively. Compared with the control group, the ICER of olaparib was $248,248/QALY. Su *et al.* (22) evaluated olaparib treatment from the perspective of United States payers, and the results showed that olaparib treatment yielded a utility of 0.063 QALYs at an additional cost of $7,382 and an ICER of $116,903/QALY compared with the standard therapeutic options, indicating that genomic analysis of olaparib treatment is the preferred option among male patients with mCRPC in the United States. From the perspectives of health services in China and the United States, the results of our study show that olaparib treatment is cost effective in mCRPC patients in the United States. However, it is not cost effective in Chinese patients with mCRPC. As revealed by sensitivity analysis, olaparib is a key influencing factor. Furthermore, adjusting the price of olaparib to a certain extent is recommended, and thus, patients can afford treatment and benefit more.

Our study has several limitations: first, in the Chinese Markov model, the WTP was 3 times the national average GDP. However, China's economic development is unbalanced. The GDP and WTP vary by region. In regions with higher GDP, treating mCRPC patients with olaparib is likely of greater economic importance. Other costs of the Chinese Markov model are incurred from a tertiary hospital in Fujian. However, the costs may vary from province to province because of the imbalance of economic development and medical resources among provinces. Similarly, the same is true for the United States Markov model, and medical decision-making authorities in the United States may adjust measures to local conditions. In addition, both models in the present study streamline disease progression because the disease may progress in 3 set states, and the patients remain in a certain state for 1 month (i.e., a cycle), though the clinical progression of mCRPC is complicated. For example, the adverse effects of drugs used in the treatment and the diversity and uncertainty of tumor progression often result in different symptoms in patients. The 2 models established in the present study are based on the ideal mCRPC progression states. Thus, the models must be realistic by adding states more suitable to complex tumor progression. However, the United States and Chinese Markov models are only set to 3 states, namely, PFS, PS, and death, because of limited data sources. Third, the composition of the trial population is complex; the samples, which may have an impact on the findings of the present study, and the utility used are mostly derived from foreign literature. However, as revealed by sensitivity analysis, the utility does not affect the robustness of the model. Finally, the results of the present study show that the price of therapeutic drugs is the key sensitive factor of the model, and anti-neoplastic drugs may be negotiated for renewal. Moreover, the prices of such drugs may drop after negotiation, thereby affecting the total cost, leading to changes in the findings and conclusions of the present study. Related health insurance policies should be paid close attention to, and adjustments to all research data should be made in a timely manner.

From the perspectives of the medical and health systems of China and the United States, all findings of our study can provide references for the clinical and rational use of olaparib among doctors and patients in China and the United States, and provide economic evidence for medical insurance re-negotiation for treating mCRPC patients in China with olaparib.

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Footnote

Reporting Checklist: The authors have completed the CHEERS reporting checklist. Available at https://atm.amegroups.com/article/view/10.21037/atm-22-3637/rc

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://atm.

amegroups.com/article/view/10.21037/atm-22-3637/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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