BMJ Open Cost-effectiveness of robotic surgery compared to conventional laparoscopy for the management of early-stage cervical cancer: a model-based economic evaluation in China

Chunlan Chen ^(D), ¹ Min Zhang, ¹ Junying Tang, ² Kexue Pu¹

ABSTRACT

Objectives The aim of this study is to assess costeffectiveness of robotic radical hysterectomy (RRH) vs laparoscopic radical hysterectomy (LRH) in early-stage cervical cancer (ECC).

Design Model-based cost-effectiveness analysis. **Setting** Based on long-term survival data, a three-state Markov model was constructed using TreeAge Pro 2022 to simulate the possible recurrence of ECC. Data on clinical efficacy and costs were derived from published literature and local databases.

Participants A hypothetical cohort of 1000 individuals diagnosed with early-stage cervical cancer (FIGO 2009 stages<IIB) who underwent RRH or LRH management. **Outcome measures** The study endpoints were quality-adjusted life years (QALYs), total costs (in Chinese renminbi (RMB) adjusted to 2023-year values using the Consumer Price Index) and incremental cost-effectiveness ratio (ICER). A willingness-to-pay threshold of 268 074 RMB per QALY was used to assess cost-effectiveness.

Results Robotic group gained more 4.84 QALYs than the laparoscopic group, but total costs for robotic strategy are substantially higher, with the incremental costs of 1 031 108 RMB. The ICER of robotic strategy is 213 054 RMB per QALY. Outcomes were robust in most one-way sensitivity and probabilistic sensitivity analyses.

Conclusions Robotic strategy is on the efficient frontier but incurs substantial initial cost. Our findings indicated that this strategy is a cost-effective treatment option for ECC patients if assessed over a time horizon of patients' lifetime. This study underscores the need for long-term clinical trials in early-stage cervical cancer patients with follow-up data that capture financial and quality-of-life end points.

INTRODUCTION

Cervical cancer currently ranks as the fourth leading cause of cancer deaths among women worldwide.¹ On 17 November 2020, the WHO released the 'Global Strategy to Accelerate the Elimination of Cervical Cancer'. The global burden caused by cervical cancer is increasingly heavy, which incurs a serious impact

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This cost-effectiveness analysis is conducted from the most appropriate and comprehensive perspective using a mathematical state transition model, where health utility is adopted as the health outcome indicator.
- ⇒ The generalisability of our results may be limited by the focus on China's social perspective, and it is not yet clear whether the trial-based study results can be extrapolated to the real world due to the lack of long-term survival outcome data from real-world patient.
- ⇒ In the present study, we do not assess the budget impact of robotic surgery on China's society, which is also an important component in the comprehensive evaluation of robotic intervention.
- ⇒ The cost-effectiveness of robotic surgery may be underestimated because cost data during the follow-up period is not currently available, and this surgery will be more favourable if the patient's postoperative sexual quality of life is assessed.
- ⇒ In future, more reasonable model structure is needed to verify our results if more detailed clinical efficacy data can be obtained; also, it is necessary to further verify the validity of our model results if longterm survival outcomes and health utilities are available from large-scale randomised controlled trials.

on local socioeconomics and people's lives. Accordingly, choosing treatment options with better therapeutic effects and lower health costs for cervical cancer patients is becoming increasingly important.

Since the first robotic radical hysterectomy (RRH) for cervical cancer was reported internationally in 2006,² many studies have shown that robotic approach had potential advantages of less blood loss, lower risk of complications, shorter length of hospital stay and more rapid patient recovery compared with conventional laparoscopic radical hysterectomy (LRH).^{3–8} With regard to long-term

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CC and MZ contributed equally.

CC and MZ are joint first authors.

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¹School of Medical Informatics, Chongqing Medical University, Chongqing, China ²Department of Gynecology, The First Affiliated Hospital of Chongqing Medical University, Chongqing, China

Correspondence to Dr Kexue Pu; pukexue@cqmu.edu.cn oncological outcomes, the estimated overall survival of RRH was lower than that of LRH with marginal significance.^{9 10} Besides, robotic approach can improve ergonomics and visualisation for surgeons.

Although the many advantages, the total cost of robotic surgery has been consistently shown to exceed that of laparoscopic surgery, mainly due to the high costs of robot equipment acquisition and maintenance as well as special disposable instruments.^{11–14} These costs currently are not included in the scope of medical insurance reimbursement for most provinces and cities in China, substantially aggravating the financial burden on society, families and patient individuals. Overall, robotic technique is on the efficient frontier but incurs substantial initial costs. On the other hand, the cost-effectiveness of robotic surgery compared with conventional laparoscopy in early-stage cervical cancer remains uncertain. Therefore, it is necessary to carry out cost-effectiveness analysis between the two surgical strategies. Cost-effectiveness analysis is a useful approach to evaluate the value of different treatment strategies by quantifying and comparing the therapy costs and effectiveness.¹⁵ With the goal of aiding decision making, we performed a model-based economic evaluation to assess cost-effectiveness of robotic strategy and laparoscopic strategy from a societal perspective in China.

METHODS Model overview

A state-transition model, also known as a Markov model, was developed using TreeAge Pro 2022 to assess the costeffectiveness of RRH compared with LRH for Chinese women diagnosed with early-stage cervical cancer (ECC) (FIGO 2009 stages<IIB). A hypothetical cohort consisted of 1000 middle-aged patients was incorporated into the Markov model, with a mean (SD) age of 45.6 (8.8) and a mean (SD) Body Mass Index of 23.00 (2.87).¹⁶ Based on the long-term survival outcomes informed by a retrospective study,⁹ the Markov model was divided into three states: disease-free survival (DFS), recurrence (including local or distant recurrence) and death. The Markov model is illustrated in figure 1. Patients underwent initial treatment with either RRH or LRH. All patients were in DFS state at the beginning of the Markov cycle. Individuals could maintain DFS state, process from the initial state to recurrence or death. ECC patients could not go back to the DFS state if they underwent local recurrence or distant metastasis, they could remain in the disease recurrence state, or process from this state to death. The Markov cycle length was set to 1 year and the time horizon was the lifetime of the cohort. According to the National Bureau of Statistics of China, the average life expectancy of the Chinese population in 2023 is 78.1 years. That is, a total of 33 cycles were simulated in this model.

Model inputs

The Markov model required a range of input parameters, including transition probabilities between health

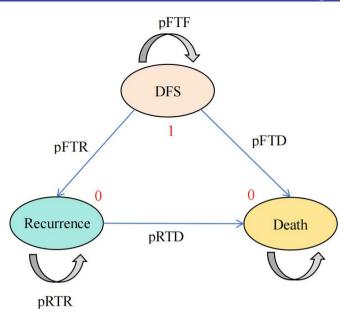


Figure 1 Markov model structure. Each circle represents a health state and arrows represent possible transitions at the end of each yearly time cycle. The initial probability of DFS, recurrence and death was set to 1, 0 and 0, respectively. DFS, disease-free survival; pFTD, probability of DFS to death; pFTF, probability of DFS to DFS; pFTR, probability of DFS to recurrence; pRTD, probability of recurrence to death; pRTR, probability of recurrence to recurrence.

states, medical costs and health-related quality of life in each health state. Values for these model parameters were informed by primary data collection and review of the literature. All input parameters used in the model analysis were listed in online supplemental table S1.

The transition probabilities were estimated based on postoperative follow-up results, including recurrence rate, overall survival rate and DFS rate after surgery. The survival data were extracted from published clinical studies.⁹ These time-to-event survival probabilities were converted into the annual hazard rate using the following formula: r = -ln[1-P(t)]/t, where r is the annual hazard rate, P(t) is the cumulative probability and t is the duration during which the probability is cumulated.¹⁷ The annual hazard rate then was converted into an annual transition probability using a Weibull parametric model using the following equation: p=1-exp(-r), where p is the annual transition probability. It was assumed that the probability of DFS state to death state is the natural mortality rate of Chinese population in 2023.

Our model incorporated direct medical costs and indirect costs. For direct costs, the following costs were included: robot equipment purchase and maintenance costs, training course fees, surgical instruments costs, operating room costs and hospital costs. The fixed costs of robot were adjusted for the lifespan of robot equipment (8 years) and the volume of operations per year (average 250, with a range of 100~300) to obtain a cost for each procedure. The instrument costs included common theatre consumables, laparoscopic consumables as well as robot-specific consumables. The costs of an (hybrid) operating room (OR) included construction and overhead costs, inventory costs including medical devices as well as personnel costs.¹⁸ OR costs, hospital stay costs and indirect costs were measured using micro-costing, where data on operating time and length of postoperative hospital stay were extracted from published clinical studies.⁹¹⁹⁻²¹ Indirect costs were based on the patient's loss of productivity. The first one considers the time during which the patient is out of work on medical leave, from the date of the procedure until the patient resumes their normal activities (ie, length of postoperative hospital stay). The calculation was based on the cost of labour from the National Bureau of Statistics of China (NBS). All costs from prior years were adjusted to 2023 Chinese renminbi (RMB) using the Consumer Price Index (CPI). The CPI information was derived from NBS.

In terms of health outcomes, we applied health utility. The utility values were obtained based on the mapping method. Xia used a Short Form 36 Questionnaire (SF-36) scale to evaluate the patients' quality of life at 1 year.²² Since the SF-36 is a non-utility scale, we converted the SF-36 quality of life score into the EuroQol Five-Dimensions (EQ-5D) health utility values required for this study by the mapping functions.²³ The quality-adjusted life years (QALYs) were obtained by multiplying the utility of a health state by the duration of the health state summed over a lifetime. In our model analysis, a standard 5% discounting rate was applied (in accordance with China Guidelines for Pharmacoeconomic Evaluations), and a half-cycle correction was used to smooth costs and utilities associated with the model.

Cost-effectiveness analysis

A cost-effectiveness analysis was performed from a China's societal perspective. The outcome was measured in QALYs and total costs. The incremental cost-effectiveness ratio (ICER) then was calculated to determined the cost-effectiveness of RRH and LRH using the following formula: ICER = $\Delta C/\Delta E$, where ΔC and ΔE represent the additional cost and additional effectiveness of robotic surgery compared with conventional laparoscopy, respectively. A willingness-to-pay (WTP) threshold of 268 074 RMB (three times China's Gross Domestic Product per capita in 2023) per QALY was used to determine cost-effectiveness. When the ICER was less than the WTP threshold, RRH strategy was considered cost-effective.

Sensitivity analyses

One-way and probabilistic sensitivity analysis were performed to assess the impact of the key model parameters uncertainty on overall model results. In the one-way sensitivity analysis, we conducted Tornado diagrams and multiple one-way sensitivity analyses to determine whether changes in the model's input parameters altered the overall outcome of the cost-effectiveness model. The range of each cost, probability and utility was based on a $\pm 25\%$, $\pm 20\%$ and $\pm 10\%$ change from the mean, respectively, where the upper limit of each probability did not exceed 1. The discount rate range is 0%~8%.

In probabilistic sensitivity analysis, probabilities and health utilities were modelled with a Beta distribution to ensure the simulation selected a value between 0 and 1. Costs were modelled with a Gamma distribution. The SD of each key model parameter was calculated by dividing the difference between the upper and lower limits by 3.92. Based on the specific distributions of key model parameters, a second-order Monte Carlo simulation was performed at random 10000 times. The results were presented as a cost-effectiveness acceptability curve.

Scenario analysis

In base case analysis, we used Chinese middle-aged patients' clinical efficacy data to conduct model analysis. To assess the impact of patient age on model results, elderly patients' data were considered in this scenario. The median age for the entire cohort was 65 (range: 61–69) years, and survival outcome information was based on data from a prospective, randomised and double-blinded study.²⁴ Date on length of postoperative hospital stay and operating time were obtained from published literature.^{24 25} All model input parameters were listed in online supplemental table S2.

Patient and public involvement

None.

RESULTS

Base-case analysis

For the ECC patients, robotic surgery instead of laparoscopy provided an additional 4.84 QALYs. Compared with the laparoscopic strategy, the mean incremental costs of robotic radical surgery were 1 031 108 RMB for the population in China. The ICER of robotic surgery

Table 1 The deterministic results from the base case analysis

Strategy	Cost (RMB)	Incremental cost (RMB)	Effectiveness (QALY)	Incremental effectiveness (QALY)	ICER (2023RMB/QALY)
LRH	1183645	_	8.65	_	_
RRH	2214753	1 031 108	13.49	4.84	213054

ICER, incremental cost-effectiveness ratio; LRH, laparoscopic radical hysterectomy; QALY, quality-adjusted life year; RMB, Chinese renminbi; RRH, robotic radical hysterectomy.

Tornado Diagram - ICER RRH vs. LRH

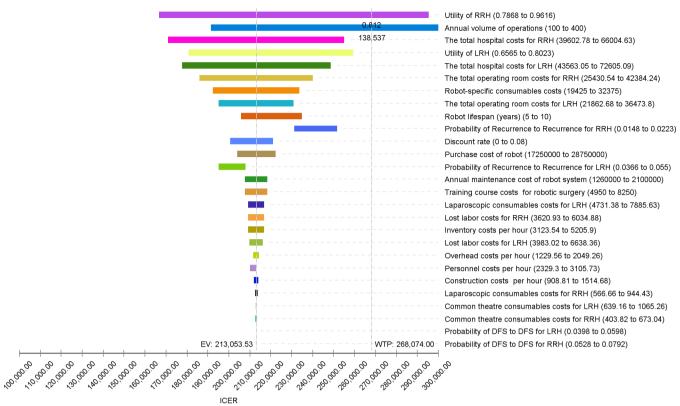


Figure 2 One-way sensitivity analysis of robotic radical hysterectomy in comparison with laparoscopic radical hysterectomy. DFS, disease-free survival; EV, expected value; ICER, incremental cost-effectiveness ratios; LRH, laparoscopic radical hysterectomy; RRH, robotic radical hysterectomy; WTP, willingness to pay.

vs laparoscopic surgery was 213 054 RMB per QALY (table 1).

Sensitivity analysis

The one-way sensitivity analysis revealed that the results of model were more sensitive to health utility values of robotic procedure because this variable had the greatest impact on ICER, which indicted that this strategy would become more favourable as the utility increased (figure 2). Another considerable influential parameter was annual volume of robotic operations. Robotic strategy was cost-effective only if over 138 robotic operations per annum, and would be more favourable as the operation volume increased.

The cost-effectiveness acceptability curve shows the chance of each strategy of being the most cost-effective for different levels of WTP (figure 3). Compared with the laparoscopic strategy, the curve showed that there would be greater certainty in favour of the robotic strategy as the WTP threshold increased. When the threshold was equal to 268 074 RMB per QALY, the robotic strategy produced nearly 65.6% probabilities of cost-effectiveness.

Scenario analysis

The scenario analysis results were presented in table 2. For elderly patients, robotic radical surgery costs 355 876 RMB more than the laparoscopic surgery over this time horizon and provided an additional 1.44 QALYs, resulting in an ICER of 247 266 RMB. At the WTP threshold of 268 074 RMB per QALY, robotic strategy was cost-effective with a probability of 50.6% (figure 4).

DISCUSSION

Compared with the conventional laparoscopic surgery, robotic surgery yielded an additional 4.48 QALYs with a substantial augment of cost, leading to average ICER of 213 054 RMB/QALY. At a WTP threshold values of 268 074 RMB per QALY gained in China, our main finding indicated that robotic surgical strategy is cost-effective option for any woman with early-stage cervical cancer who is an appropriate candidate if assessed over the lifetime of patients. The cost-effectiveness acceptability curve also demonstrated this finding that a majority of certainty was achieved by robotic strategy at the threshold of 268 074 RMB/QALY.

The strength of the present evaluations is that it is the first to investigate the cost-effectiveness of robotic radical hysterectomy for patients with early-stage cervical cancer from the most appropriate and comprehensive perspective (a China's societal perspective), and our results are



CE Acceptability Curve

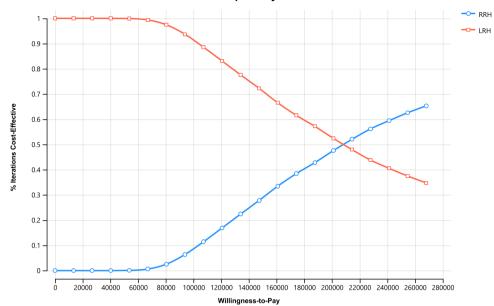


Figure 3 The cost-effectiveness acceptability curve for robotic strategy compared with laparoscopic strategy. CEAC shows the probability of each strategy being the most cost-effective as a function of the WTP threshold. CEAC, cost-effectiveness acceptability curve; LRH, laparoscopic radical hysterectomy; RRH, robotic radical hysterectomy; WTP, willingness to pay.

of great significant in China. Besides, this is one of few economic evaluations using model analysis methodology and adopting health utility as a health outcome indicator, which can fully and comprehensively reflect the changes in patients' health status and subjective feelings caused by diseases or interventions. Modelling analysis can more effectively combine multiple resources to simulate the occurrence and progression of diseases. Specially, the state transition probabilities of Markov model were calculated based on long-term survival data, which reasonably solved the problem of time dependence of transition probability in the dynamic Markov model. We used the model to estimate long-term costs and health outcomes of patients under different interventions, providing a more sufficient basis for decision-making for medical and health decision-makers.

Like most modelling analysis, ours has limitations. First, the generalisability of our results may be limited by the focus on the social perspective in China. Given that, all input parameters in our model analysis were presented transparently to enable calculation of reliable estimates for other countries as well. Second, the transferability of the present analysis results needs to be further verified. It is not yet clear whether the trial-based study results can be extrapolated to the real world due to the lack of long-term survival outcome data from real-world patient. Third, the budget impact of robotic treatment on China's society has not been considered in this study. The results of budget impact analysis play an important role in market access, price negotiation, volume procurement, risk-sharing agreements and other application scenarios. Fourth, the costeffectiveness of robotic surgery may be underestimated because we had no cost data during the follow-up period (like readmission costs, disease recurrence costs). Also, robotic treatment will be more favourable if the patient's postoperative sexual quality of life is assessed. Fifth, we did not make a detailed classification of the types of disease recurrence and simply divided Markov model into three health states because of the absence of more detailed clinical efficacy data, which may lead to an underestimation of the cost-effectiveness of robotic surgery. In real world, there are differences in treatment methods, patient health outcomes and disease prognosis for different recurrence types. If more Markov states would be included in our model, this may bring more accurate results. Finally, it is necessary to further verify the validity of our model results if long-term survival outcomes and health utilities are available from large-scale randomised controlled trials.

Table 2 The deterministic results from the scenario analysis								
Strategy	Cost (RMB)	Incremental cost (RMB)	Effectiveness (QALY)	Incremental effectiveness (QALY)	ICER (2023RMB/ QALY)			
LRH	1 120 97 1	_	6.56	_	_			
RRH	1 476 847	355876	8.00	1.44	247266			

ICER, incremental cost-effectiveness ratio; LRH, laparoscopic radical hysterectomy; QALY, quality-adjusted life year; RMB, Chinese renminbi; RRH, robotic radical hysterectomy.

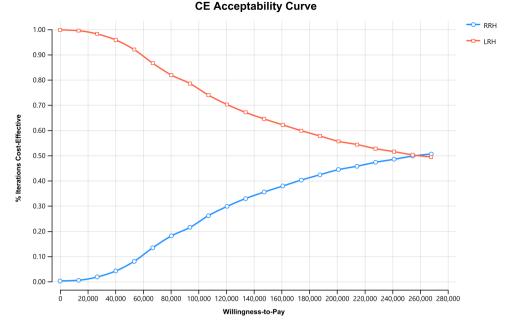


Figure 4 Probabilistic sensitivity analysis results in the scenario analysis. LRH, laparoscopic radical hysterectomy; RRH, robotic radical hysterectomy.

Previously, most of economic evaluations on robotic hysterectomy were conducted based on prospective or retrospective observational study. Moreover, these studies only consider costs or the economic burden of disease, which are not true cost-effectiveness studies.^{13 14 26–32} For example, Zakhari *et al*^{a^2} compared the costs and complications among women undergoing robotic and laparoscopic hysterectomy for uterine cancer by carrying out a retrospective cohort study. Additionally, Iavazzo *et al*¹² tried to assess the cost-benefit of the robotic surgery in gynaecological oncology by a systematic review. In modelbased economic evaluation studies, $^{33-35}$ Telijeur *et al*^{β 4} indicated that robot-assisted hysterectomy is more costly than traditional laparoscopic surgery, and the additional costs of robotic surgery may not be justified in a budgetconstrained health system, without longer-term or functional outcome data.³⁴ In the present study, QALY was taken as health outcome indicator, which comprehensively considers the impact of interventions on patient survival time and quality of life. Our findings indicated that robotic strategy is on the efficient frontier, yielding 4.84 QALYs more than laparoscopic strategy, which may be explained by better quality of life after surgery. Robotic surgery can reduce bleeding and overall complications, as well as relieve patient pain and speed up postoperative recovery. Consistent with previous findings,^{26 27 32 34 36 37} we also found that robotic surgery was substantially more expensive compared with the conventional laparoscopy (incremental costs of 1 031 108 RMB). The additional cost of robotic surgery is primarily driven by the capital costs of robot system (the purchase and maintenance costs) and the robot-specific surgical consumable costs, which is not compensated by the lower hospital room costs. In China, the cost of robotic equipment and accessories is approximately 44 000 RMB, of which capital costs account

for 18 000 RMB. According to a cost-effectiveness analysis by Leitao *et al*^{b^{5}} laparoscopic approach is least expensive when including the capital acquisition costs, while the two surgical routes are comparable if upfront costs are excluded. For surgery costing, some studies did not account for the fixed capital costs of robotic system.^{27-30 37} This economic evaluation was conducted from a societal perspective, including direct costs and indirect costs, which was similar to a previous cost-minimisation analvsis by Martínez-Maestre et al.²⁶ Differently, the authors assumed that robotic and laparoscopic procedures were clinically equivalent, and only the costs were considered and evaluated, without taking into account the health outcomes.²⁶ Our study has demonstrated that robotic approach is cost-effective when evaluating long-term survival outcomes from the point of view of an economic analysis based on cost-effectiveness, but Martínez-Maestre et al concluded that laparoscopic approach is the more efficient option-based cost-minimization.²⁶ More specially, we performed incremental cost-effectiveness analysis (calculated ICER value) to determine the costeffectiveness of robotic surgery vs laparoscopy. The incremental analysis indicated that the incremental cost increased by 213 054 RMB for each additional QALY gained, which <a WTP threshold of 268 074 RMB. Therefore, robotic surgery is a cost-effective option for ECC patients. Since the endpoint indicators (ie, long-term efficacy indicators) are difficult to obtain directly in a short period of time during clinical treatment, many authors use the critical intermediate indicators (ie, short-term effect indicators) to perform economic evaluation. For example, Qiu et al performed a cost-effectiveness analysis using short-term clinical outcomes and costs during hospitalisation.³⁸ Their findings indicated that robotic surgery can dissect more pelvic and abdominal lymph nodes than laparoscopic technique, but with total additional cost of 32 000 RMB. Given that, the authors believed it is difficult to demonstrate that robotic surgery is cost-effective based on short-term clinical indicators alone. Considering the incremental costs associated with surgical site infections and blood transfusions, Swenson *et al*²⁷ found that the additional cost of robot-assisted hysterectomy was \$3269 per case compared with laparoscopic surgery. The authors maintained that it is hard to estimate whether robotic route is cost-effective because this strategy did not significantly reduce the clinically and financially burdensome complications.²⁷ Additionally, sensitivity analyses were conducted to verify the robustness of the model results in this study. In one-way analyses, we must acknowledge that health utility values of robotic procedure have the largest impact on the overall model results. The health utility reflects the patient's postoperative quality of life after robotic surgery, and we found this strategy is cost-effective when the utility value is greater than 0.81 and will become more favourable as the utility increases. Finally, we conducted a scenario analysis to investigate the impact of patients' age on the cot-effectiveness of robotic strategy. The results of scenario analysis indicated that the ICER was 247 266 RMB (<the WTP threshold of 268 074) for elderly patients, which was higher than that from the base-case analysis (the ICER was 213 054 RMB for middleaged patients). At the WTP threshold of 268 074 RMB per QALY, robotic strategy produced nearly 50.6% probabilities for the elderly patients (less than 65.6% probabilities of cost-effectiveness for the middle-aged patients). These results can be attributed to the fact that higher operating room costs and hospital costs for older patients, resulting from longer operative times and slower postoperative recovery.

Currently, economic evaluation mainly focuses on drugs but lacks evaluation on new medical equipment and new health technologies. With the rapid development of robotic technology in the medical field, assessing whether such a surgical technique is cost-effective compared with non-robotic technique is becoming increasingly important. Cost-effectiveness analyses are needed to provide decision makers at all levels (like surgeons, patients and health decision-making department) with scientific information and decision-making support for reasonable selection of medical devices. Our findings indicated that robotic surgical strategy is cost-effective treatment option for women with earlystage cervical cancer if assessed over a time horizon of the patients' lifetime. Thereby, we support the promotion and application of robotic technology in the field of gynaecological malignant tumours, especially for younger patients with early-stage disease. This work may provide a reference for surgeons and patients to reasonably choose surgical options and provide health decision-making department with scientific information and decision-making support for rational allocation and management of robotic system.

CONCLUSIONS

Our analysis indicates that robotic radical hysterectomy can be cost-effective for women with early-stage cervical cancer, especially for younger patients. To make robotic strategy more cost-effective, the patient's postoperative quality of life after robotic surgery should be improved. Also, cost-effectiveness depends on the annual volume of robotic operations at centres equipped with a robot system. Of course, it will be conducive to the promotion of robotic technology routine clinical practice if the initial capital cost of robot can be reduced to a level that may be accepted by all stakeholders.

Contributors PK obtained funding. CC, MZ, PK and JT designed the study. CC, MZ, PK and JT collected the data. Model analyses were by CC and MZ. The manuscript was drafted by CC and all authors contributed to revising the manuscript and approved the final version of manuscript. PK is the study guarantor.

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ORCID iD

Chunlan Chen http://orcid.org/0009-0008-9995-0693

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