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On May 19, 2023, PKU Institute for Globe Health and Development has launched the Survey of Medical Assessment for Robotic Technology (SMART), a longitudinal multi-center study in China. In order to ensure the SMART study progress to be updated timely and effectively among all the participants, The SMART Surgical Quarterly is launched accordingly as an internal journal. This quarterly journal will serve as a comprehensive platform to update the key information on the SMART progress as well as the progress for the parallel studies.

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目　　录

平 行 研 究

Does Robotic Surgery Help Reduce the Economic Burden of Malignant Tumors in the Pancreas? A Cost-of-Illness Study

By YIN SHI, ZITING WU*

Abstract: This study focuses on the impact of robotic surgery on the economic burden of pancreatic malignancies, falling under the scope of micro-cost research. Since the first report of laparoscopic pancreatoduodenectomy (LPD) in 1994, the application of laparoscopic or robot-assisted techniques in pancreatic surgery has garnered significant attention. However, debates persist regarding their oncological efficacy and surgical safety in radical treatments for pancreatic cancer, and the economic benefits of robotic surgery remain unclear. In this study, information such as surgical details, and costs were obtained from the hospital medical record. Transportation, accommodation, nutrition, and time costs during patients' medical treatment were collected through questionnaires. In this stage, operation time and diseased site have been cleaned. The average operation duration of robotic surgery patients is relatively shorter than that of other surgical methods. Among patients who underwent robotic, laparoscopic, and open surgeries, most common disease location is the pancreatic tail, accounting for 54.7%, 75.8%, and 57.1% respectively. Data on out-of-hospital costs at discharge and 90 days post-discharge were also collected, time costs for both patients and family members were lower in the robotic surgery group. To date, 4,713 cases of in-hospital cost data, 105 cases of discharge out-of-hospital data, and 75 cases of 90-day post-discharge out-of-hospital data have been collected.

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I. Background and Objective

Since the first laparoscopic pancreatoduodenectomy (LPD) was reported in 1994, the exploration of the application of laparoscopic or robotic technology in pancreatic surgery has been ongoing (Shah and Singh 2024). Currently, the controversy over the application of laparoscopic or robot-assisted surgery for curative treatment of pancreatic cancer mainly focuses on the oncological evaluation of treatment effects and surgical safety. Regarding laparoscopic or robot-assisted radical surgery for pancreatic cancer, Chinese experts discussed its efficacy and safety in the 2022 consensus, believing that minimally invasive radical surgery has a broad application prospect (Study Group of Minimally Invasive Treatment for Pancreatic Cancer in China Anti-Cancer Association and Chinese Pancreatic Surgery Association 2023). Robotic surgery is associated with high costs, but patients experience faster recovery and fewer complications. The economic benefits of robotic surgery, compared to traditional surgical methods, remain inconclusive.

This research progress report consists of two parts: first, a detailed report on the data cleaning process and its results; second, a report on the data acquisition status.

II. Methods

We obtained patients' basic characteristics, surgical information, pathological stages, and cost information from the hospital medical record front page and surgical records. The specific variables include gender, age, marital status, communication address, admission date, admission department, discharge date, main diagnosis, treatment outcome, attending physician, medical insurance type (urban employee / urban - rural resident / uninsured), operation date, operation start time, operation end time, operation type, operation name, intraoperative blood loss, complications, pathological stage, total cost, bed fee, nursing fee, western medicine fee, radiology fee, blood transfusion fee, consultation fee, operation fee, inspection fee, etc. Through the questionnaire survey method, we obtained direct non-medical costs, including transportation, accommodation, and nutrition costs, as well as indirect costs, including economic losses caused by work absences of patients and their family members.

Based on the operation start time and operation end time in the acquired data, all times were standardized to 24 - hour format and calculated in hours. Operation duration (hours)=Operation end time (hours) - Operation start time (hours).

According to the text description in the pathological stage, relevant keywords were extracted to obtain information on the main diseased site. The main diseased sites include the pancreatic head, pancreatic neck, pancreatic body, pancreatic tail, and total pancreas.

Key terms from pathological staging reports were used to identify the primary disease location: pancreatic head, neck, body, tail, or entire pancreas. Due to non-standardized text descriptions, manual judgment was applied for ambiguous cases. (1) Pancreatic tail: Pathological pancreatic tail, pancreatic body-tail, pancreatic tail, pancreatic body-tail part, pancreatic main pancreatic duct mucinous cystadenoma, pancreas (body-tail, body-tail part, body-tail, pancreas (tail, pancreas (tail, tail part); (2) Pancreatic head: Pancreatic head, pancreatic head part, pancreatic head region, pancreatic uncinate process; (3) Pancreatic neck: Neck, pancreatic neck, pancreas neck, pancreatic mid - segment, mid - segment; (4) Pancreatic body: Pancreatic body part, etc. (5) Total pancreas: If the keywords in (1), (2), (3), and (4) do not appear in the pathological text, or if the pancreatic lesion is directly described.

We intended to describe the TNM staging information of pancreatic cancer. Currently, it is difficult to extract TNM information or the information is incomplete from the extracted pathological stage information, and manual judgment of TNM staging is required. We need to further attempt to directly retrieve standardized TNM staging information from the hospital medical record front page.

The interpretation of the TNM staging of pancreatic cancer is as follows:

- Tumor size (T)
- Whether cancer cells have spread to the lymph nodes near the cancer (N)
- Whether the tumor has metastasized to other parts of the body (M). Doctors refer to metastasized cancer as secondary cancer or metastatic cancer.

The TNM system is used for cancer staging worldwide. It is important for doctors to use the same staging system so that they can compare when discussing the same disease.

The tumor size (T) is divided into 5 stages:

- Tis (carcinoma in situ) is a very early - stage pancreatic cancer that has not had the opportunity to spread. This type of cancer is rare.
- T1 refers to a tumor within the pancreas that is no larger than 2 cm.
- T2 refers to a tumor that is still within the pancreas and is larger than 2 cm when measured from any direction.
- T3 means that the cancer has begun to invade the tissues around the pancreas, but it has not invaded the nearby large blood vessels.
- T4 indicates that the cancer has further spread to tissues or organs far from the pancreas and has invaded nearby large blood vessels.

The lymph node (N) staging of the tumor:

- N0 means that there are no cancer cells in the lymph nodes.
- N1 means that there are lymph nodes containing cancer cells, so the cancer is more likely to spread beyond the pancreas.

The M staging of the tumor:

- M0 refers to cancer that has not metastasized to distant organs such as the liver or lungs.
- M1 means that the cancer has metastasized to other organs.

III. Results

A.Data Cleaning Results

1. In - hospital Data Cleaning

(1) Operation Duration (hours)

The in - hospital data of 1730 cases have been cleaned. Among them, 99.54% (1722/1730) of the operation time was reported completely. The average operation duration is 5.8 hours (standard deviation 1.80). There were 972 cases of robotic surgery (including robot + laparoscopy, robot + laparotomy), with an average operation duration of 5.62 hours (standard deviation 1.69); 148 cases of laparoscopic surgery (including laparoscopy + laparotomy), with an average operation duration of 6.54 hours (standard deviation 1.85); and 495 cases of open - surgery, with an average operation duration of 5.92 hours (standard deviation 1.89). The operation durations and diseased sites of patients with different surgical types are shown in Table 1. The average operation duration of robotic surgery patients is relatively shorter than that of other surgical methods.

TABLE 1 - OPERATION DURATION FOR PATIENTS OF DIFFERENT SURGICAL TYPES (HOURS)

Surgical Type	**Operation Duration (hours) (Mean ± SD)**
LS (including LS+OS)	6.54±1.85
RS (including RS+LS, RS+OS)	5.62±1.69
OS	5.92±1.89
Total	5.80±1.80

Note: LS, laparoscopy surgery; OS, open surgery; RS, robot assisted surgery.

(2) Diseased Location

The in-hospital data of 1730 cases have been cleaned, and the diseased location information can be extracted in 93.99% (1626/1730) of the cases. Among them, 0.18% (3/1626) of the main diseased location are not on the pancreas. Among the 1623 cases with the main diseased location on the pancreas, the pancreatic tail accounts for the highest proportion of 57.7% (936/1623), followed by the total pancreas with 26.4% (429/1623) and the pancreatic head with 11.8% (191/1623) (Table 2). Among patients with different surgical types, the proportion of the pancreatic tail as the disease location is the highest in patients who underwent RS (including RS+LS, RS+OS), LS (including LS+OS), and OS, accounting for 54.7%, 75.8%, and 57.1% respectively (Table 1).

TABLE 2 - DISEASE LOCATION

Diseased Site	Overall	LS (including LS+OS)	RS (including RS+LS, RS+OS)	OS
Whole Pancreas	429 (26.4%)	24 (16.1%)	301 (31.0%)	103 (20.4%)
Pancreatic Neck	27 (1.7%)	0	13 (1.3%)	14 (2.8%)
Pancreatic Neck + Pancreatic Body	4 (0.2%)	0	2 (0.2%)	2 (0.4%)
Pancreatic Neck + Pancreatic Body + Pancreatic Tail	8 (0.5%)	1 (0.7%)	4 (0.4%)	3 (0.6%)
Pancreatic Body	23 (1.4%)	1 (0.7%)	9 (0.9%)	13 (2.6%)
Pancreatic Head	191 (11.8%)	10 (6.7%)	110 (11.3%)	71 (14.1%)
Pancreatic Head + Pancreatic Neck + Pancreatic Body	1 (0.1%)	0	0	1 (0.2%)
Pancreatic Tail	936 (57.7%)	113 (75.8%)	531 (54.7%)	288 (57.1%)
Pancreatic Tail + Pancreatic Head	2 (0.1%)	0	0	2 (0.4%)
Pancreatic Tail + Pancreatic Head + Pancreatic Neck	2 (0.1%)	0	0	2 (0.4%)

Note: LS, laparoscopy surgery; OS, open surgery; RS, robot assisted surgery.

2. Out-of-hospital and Follow-up Data

The out - of - hospital data (at discharge + 90 - day follow - up) of 75 cases have been cleaned. The total time cost of patients is 6346 yuan; the total time cost of family members is 11612 yuan; the average transportation cost per case is 5134 yuan, the patient's accommodation cost is 2982 yuan, the accommodation and bedside care cost of family members is 2388 yuan, and the patient's nutrition cost is

660 yuan. The average non - medical costs and indirect costs of patients with different surgical types are shown in Table 3. The time costs of robotic surgery patients and their family members are lower.

TABLE 3-NON-MEDICAL EXPENSES AND INDIRECT COSTS FOR PATIENTS OF DIFFERENT SURGICAL TYPES (CNY)

Surgical Type		Transportation	Accommodation (F)	Accommodation (P)	Nutrition	Time Cost (P)	Time Cost (F)
LS	Overall	4382	920	657	270	8396	15595
	At Discharge	3560	920	590	270	7384	13265
	90 Days after Discharge	822	0	67	0	1012	2330
RS	Overall	4752	2298	3535	811	5593	10622
	At Discharge	4038	2283	3017	796	4796	7892
	90 Days after Discharge	714	15	518	15	797	2730
OS	Overall	6150	3189	3007	550	6813	11680
	At Discharge	5037	3031	2725	287	5531	7661
	90 Days after Discharge	1113	158	282	263	1282	4019
Total	Overall	5134	2388	2982	660	6346	11612
	At Discharge	4280	2331	2604	570	5367	8538
	90 Days after Discharge	854	57	378	90	979	3074

Note: LS, laparoscopy surgery; OS, open surgery; RS, robot assisted surgery; F, family member; P, patient.

B.Research Data Acquisition Progress

1.*Direct Non-Medical and Indirect Costs through Surveys.* The direct non-medical costs and indirect costs were obtained through the questionnaire survey method. Currently, the cost collection of 105 patients at discharge and the cost information of 75 patients 90 days after discharge have been completed.

Medical Costs through Hospital Data Extraction.

2.The medical costs were obtained through the method of in-hospital data transcription. Currently, a total of 12166 patients who underwent robotic / laparoscopic / open pancreatic resection from January 1, 2014, to September 12, 2024, have been screened in the hospital system based on surgical method keywords. Combined with the diagnosis, 4713 cases of pancreatic malignancies were further screened. In the future, cases of patients diagnosed with malignant tumors in the ampullary region who are confirmed to have pancreatic malignancies will continue to be screened. Currently, the information transcription of 4713 patients with pancreatic malignancies has been completed.

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Health Economics Evaluation of Robot-assisted Intertrochanteric Fracture Surgery Based on Real-World Data

By ZHANG GONGZI, YAO YAO, JIANG SHAOXIANG *

I. Background

The number of patients with osteoporosis is increasing with an aging population (Curry SJ et al., 2018). Hip fracture (HF), the most serious complication of osteoporosis, is expected to increase to 4.5 million by 2050, with about half of the new cases likely to occur in Asia (Troels MJ et al., 2024). Hip fractures place a heavy burden on the health-care system, costing the U.S. about $6 billion annually (Tajeu GS et al., 2024). Hip fractures are associated with higher mortality, disability risk, and rehospitalization rates, with intertrochanteric fractures accounting for approximately 45%, with a 1-year mortality rate of 14% to 36%, and 20% of fracture patients requiring long-term care (Bhandari M et al., 2019; Thach T et al., 2022).

In recent years, with the advancement of technology and the reduction of production costs, the surgical robots have been rapidly developed in the field of orthopaedics. Surgical robots can provide surgeons with preoperative planning simulation, intraoperative navigation, and minimally invasive precise positioning, effectively improving surgical quality and reducing intraoperative risks (Kayani B et al., 2018). In the treatment of intertrochanteric femoral fractures, closed reduction and intramedullary nailing internal fixation is considered as the preferred procedure due to its minimally invasive nature and good biomechanical properties. Accurate internal fixation screw placement plays a key role in maintaining the stability of the fracture end, promoting bone healing, and reducing the risk of postoperative complications. In particular, the accurate positioning of the ideal entry point is an important technical point for the success of the operation, which

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directly affects the following aspects: 1) maintenance of anatomical alignment of the fracture; 2) avoidance of re-fracture around the internal fixation; and 3) minimisation of medical damage to the gluteus medius muscle (Kaplan K et al., 2008). Therefore, precise intraoperative selection and positioning of the nail insertion point is the core of the operation to ensure the efficacy of the operation and to reduce the related complications. A meta-analysis indicated that compared with the traditional operation, the robot-assisted nail insertion operation significantly reduced the amount of intraoperative bleeding, the number of times of the guide pin penetration and the exposure time to radiation, and improved the accuracy of the screw position, but there was no significant difference in the operation time between the two groups (Al-Naseem et al., 2008). Lan et al. reported that robotic-assisted positioning of the proximal pinning point of intertrochanteric fractures showed that robot-assisted surgery significantly reduced intraoperative blood loss, number of guide pin insertion attempts, radiation exposure time, and improve the success rate of ‘one-time insertion’ of the pins, when compared with the traditional surgical methods.

II. Methods

A real-world study was conducted to retrospectively collect all patients aged 60 years and older diagnosed with intertrochanteric fractures between January 2019 and December 2021. Exclusion criteria included a history of previous hip fracture, and missing data (with key information such as treatment plan and hospitalization costs). We extracted the following data from each medical record: gender, age, comorbidities, blood transfusion status, ICU admission record, anaesthesia mode, length of hospital stay, hospital grade and type, hospital costs and information on readmission due to secondary fracture. Death data were obtained from the Beijing Municipal Centre for Disease Control and Prevention database and were matched with the patient's unique code in the hospitalisation record, while the specific date and cause of death were extracted.

The study constructed Markov models based on TreeAge Pro software for estimating the total cost of treatment and quality-adjusted life years (QALYs) over a 3-year period. Through cost-effectiveness analysis, we calculated the incremental cost-effectiveness ratio (ICER), which is the additional cost per QALY gained or unit of prolonged survival time, compared between conventional intramedullary nailing placement, conventional extramedullary fixation, robot-assisted intramedullary nailing placement, and conservative treatments, to determine the most cost-effective treatment option.

III. Results

After screening by inclusion and exclusion criteria, a total of 16,238 patients were enrolled in this study and were divided into conventional intramedullary treatment group (7,896 patients), conventional extramedullary treatment group (5,447 patients), robotic-assisted intramedullary placement group (608 patients), and conservative treatment group (2,287 patients) according to the surgical approach.

The results of the study showed that the use of robot-assisted nail placement led to an increase in treatment costs. The median treatment cost for femoral intertrochanteric fractures of the femur increased by $4,884.9 (52.9% increase) [from $9,230.6 (interquartile range: $4,649.7-$12,252.0) to $14,115.5 (interquartile range: $9,862.4-$18,332.7)] in 2021 compared to 2019, whereas over the same time period The per capita cost of conservative treatment increased by only $382.6 [from $1,879.6 (interquartile range: $733.1-$5,691.2) to $2,262.6 (interquartile range: $1,055.4-$5,414.9)]. The median cost of treatment for patients undergoing robotic-assisted surgery was $1,223.8 (9.5% increase) higher than that of patients undergoing conventional nail placement [$14,086.0 (interquartile range: $11,695.4-$17,230.9) vs. $12,862.2 (interquartile range: $9,600.6-$16,716.0)].

The study further compared the incremental costs and incremental QALYs of the three surgical modalities relative to conservative treatment. The results showed that the highest quality-adjusted life years (QALYs) were obtained with conventional intramedullary nailing, followed by conventional extramedullary treatment, robotic-assisted surgery, and conservative treatment (Table 1). Based on the willingness-to-pay (WTP) threshold analysis, Figure 1 shows that conventional intramedullary nailing is the most cost-effective treatment strategy. In the cost-effectiveness boundary analysis, traditional intramedullary nailing was the most cost-effective (ICER = $1,273.48 per 1% improvement in survival and $31,354.20 per QALYs obtained), followed by robotic-assisted surgery ($2,249.25 per 1% improvement in survival and $45,406.31 per QALYs obtained) and conventional extramedullary therapy ($3,879.61 per 1% improvement in survival and $51,679.28 per QALYs obtained).

TABLE 1-COST-EFFECTIVENESS ANALYSIS BETWEEN DIFFERENT TREATMENT MODALITIES FOR INTERTROCHANTERIC FRACTURES, 2019 TO 2021

	Robotic-assisted intramedullary surgery	Intramedullary implants	Extramedullary implants	Conservative treatment
Costs per person	52082.1 ($14086.0)	45170.9 ($12862.2)	50488.3 ($14191.8)	7792.8 ($2165.0)
Effectiveness				
Total QALYs per person	1.889	1.945	1.905	1.683
1 year	0.661	0.672	0.663	0.617
2 year	0.625	0.645	0.630	0.544
3 year	0.603	0.628	0.612	0.522
ICER				
ΔCosts/ΔQALYs	$45406.31	$31354.20	$51679.28	Ref

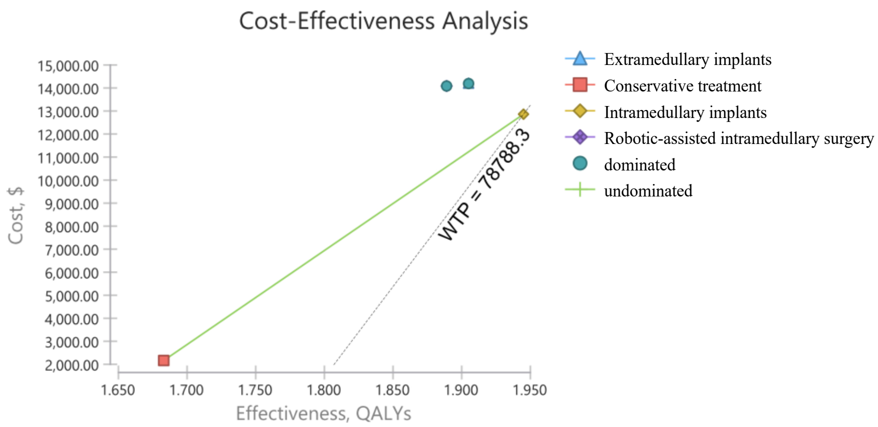

FIGURE 1. COST-BENEFIT ANALYSIS OF DIFFERENT SURGICAL STRATEGIES FOR INTERTROCHANTERIC FRACTURES

IV. Conclusions

Robotics started to be used for assisted nailing of intertrochanteric fractures between 2019 and 2021, but the amount of application was low and did not show significant benefits in reducing postoperative mortality or secondary fracture risk in patients and also for the ability to significantly increase the quality of life adjusted years of the patient postoperatively. And due to the high overall costs of surgery, it did not show a good cost-benefit. The reason for this may be that the robot is initially used in the clinic and the surgical technique is not yet mature, the next step of the study is to continue to expand the sample to include the population from 2021 to 2024, and to expand the scope of orthopaedic surgery to include joint replacement and spinal surgery patients.

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Clinical Efficacy and Health Economics Research of Orthopedic Surgical Robot-Assisted Surgery Versus Conventional Surgery: A Multicenter, Observational, Retrospective Cohort Study

By SHUJUN LIN, JIAN MO AND HAOXIANG LIN*

The advent of surgical robots has effectively shortened the learning curve for minimally invasive surgery among surgeons, improved their training efficiency, and enhanced the quality of surgical education. This study aims to evaluate the differences in learning curves, clinical efficacy, and health economics between robot-assisted surgery and conventional surgery using real-world data through a retrospective cohort study. This study will compare the accuracy of screw placement between surgeons in the conventional surgery group and the robot-assisted surgery group. Secondary outcomes include complication rates, operative time, functional scores of patients, treatment costs, and other relevant indicators.

I. Introduction

Orthopedic surgical robots represent a branch of robotic clinical applications, originating in the early 1990s. For instance, the world's first robotic spine surgery platform (Robotic Spine System, RSS) was approved by the U.S. Food and Drug Administration (FDA) in 2004 (D'Souza M et al, 2019). Since then, robot-assisted placement of thoracolumbar pedicle screws has been extensively studied. The TiRobot Orthopedic Surgical Robot (produced by Beijing Tinavi Medical Technologies Co., Ltd., China) is the first domestically developed orthopedic surgical robot approved by the Chinese FDA (Tian et al, 2017). In 2015, it successfully performed the world's first robot-navigated cervical spine internal fixation surgery and has since been utilized in various procedures, including spinal and joint surgeries. Surgical robots enable preoperative planning, simulation, and intraoperative navigation, ensuring precise execution of surgical plans (Bao et al,

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2024). Currently, robot-assisted screw placement is the most mature and widely adopted application in spinal surgery, offering superior accuracy and safety compared to conventional methods. It reduces complications, minimizes radiation exposure for both surgeons and patients, decreases trauma, and shortens operative time (Caelers et al, 2023).

To evaluate the training process and quality of orthopedic surgeons, the learning curve is a well-established framework. Commonly used parameters include operative time, hospital stay, and complication rates, which are critical for assessing surgical efficiency and outcomes (Soomro et al, 2020). This study employs a real-world research design and retrospective cohort analysis to compare the learning curves, clinical efficacy, and health economics between robot-assisted and conventional surgeries. The findings will provide evidence-based insights into the clinical and economic advantages of surgical robots, aiding healthcare policymakers, clinicians, medical device manufacturers, patients, and insurance providers in decision-making. This research will also address the growing demand for orthopedic care in aging societies.

II. Methods

Design

A multicenter, observational, retrospective cohort study was conducted, led by the Third Affiliated Hospital of Sun Yat-sen University, with participation from other institutions such as Beijing Jishuitan Hospital.

Population

Patients diagnosed with lumbar disc herniation, lumbar spondylolisthesis, lumbar spinal stenosis, degenerative lumbar scoliosis, thoracolumbar fractures, or requiring limb/joint surgeries were recruited from participating hospitals. The study included 20 surgeons and 600 patients.

Protocol

Surgeons were divided into two groups: conventional surgery and robot-assisted surgery. Surgeons in the conventional group performed standard lumbar procedures under the guidance of experienced associates or chief physicians, while the robot-assisted group utilized the TiRobot system for surgical planning and execution.

Primary Outcome

Accuracy of screw placement between the two groups, evaluated using the Gertzbein-Robbins grading system.

Secondary Outcome

Complication rates, operative time, intraoperative blood loss, hospital stay, patient functional scores, readmission rates, surgical costs, and total treatment expenses.

Statistical Analysis

Data were analyzed using Stata 18.0 and SPSS 19.0. Continuous variables were expressed as mean ± standard deviation (X ± SD), and categorical variables as frequencies and percentages. For normally distributed data with homogeneity of variance, difference-in-differences (DID) models, cross-sectional regression, and independent t-tests were applied. Non-parametric tests (e.g., Mann-Whitney U test) were used for non-normal distributions. Categorical data were analyzed via chi-square or Fisher's exact tests. Logistic regression was employed to assess baseline factors affecting outcomes, with results reported as odds ratios (OR) and 95% confidence intervals. A p-value <0.05 was considered statistically significant. Bonferroni correction addressed multiple testing issues. Sensitivity analyses and subgroup analyses were conducted to ensure robustness. Missing data were managed using multiple imputation and rigorous follow-up protocols.

III. Discussion

The adoption of orthopedic surgical robots can shorten learning curves, enhance surgical training efficiency, and reduce complications, contributing to equitable healthcare outcomes. This multicenter study, involving the Third Affiliated Hospital of Sun Yat-sen University and Beijing Jishuitan Hospital, has completed questionnaire development and is undergoing ethical review. Significant progress is expected by late 2025, with findings on learning curves and cost-effectiveness analyses providing critical insights for evaluating robotic surgery's clinical and economic impact.

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Cost-effectiveness analysis of robot-assisted laparoscopic surgery and conventional laparoscopic surgery in the treatment of early-stage endometrial cancer: a model-based health economic evaluation in China

BY MIN ZHANG, KEXUE PU*

To evaluate the cost-effectiveness of robot-assisted laparoscopic surgery (RALS) versus conventional laparoscopic surgery (CLS) in the treatment of early-stage endometrial cancer (EC). This study was undertaken from a Chinese societal perspective with a lifetime horizon. The primary evaluation indicators include the cumulative costs, Quality-Adjusted Life Years (QALYs), and Incremental Cost-effectiveness Ratio (ICER). The results suggested that RALS does not demonstrate superior cost-effectiveness compared to CLS. Univariate sensitivity analysis indicated that, as the annual operation volume for RALS increased, the ICER decreased. Especially, when the annual operation volume per robotic device reaches 947 cases, RALS will emerge as a more cost-effective surgical strategy. The probabilistic sensitivity analysis revealed that that RALS becomes more cost-effective when the WTP threshold exceeds¥357,809.40.From the Chinese societal perspective, at a WTP threshold of ¥275,238/QALY, RALS is unlikely to be a cost-effective treatment option for early-stage EC compared to CLS. RALS can become cost-effective with the increased annual operation volume and the elevated WTP threshold.

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I. Introduction

Endometrial cancer (EC) is the sixth most common malignancy among global women, yet it ranks first in incidence among gynecological cancers in developed nations（Bray et al.,2024）. Although previous studies have indicated that the incidence of endometrial cancer is relatively low in Asian populations（Katagiri et al.,2023）, China has emerged as a region with a notably high incidence of EC, as evidenced by recent statistics revealing 84,520 new cases and 17,543 deaths attributed to the disease in 2022 . The majority of EC patients are diagnosed at an early-stage disease confined to the uterus, timely treatments, such as surgical intervention, have been shown to achieve high cure rates（Gu, et al.,2021）.

The treatment of EC has historically relied primarily on surgical intervention, with postoperative radiotherapy and chemotherapy serving as adjunctive therapies（Wijayabahu et al.,2024）. Surgical intervention is the preferred approach for early-stage EC, with the standard surgical approach being total hysterectomy with bilateral salpingo-oophorectomy. Currently, laparotomy, conventional laparoscopic surgery (CLS), and robot-assisted laparoscopic surgery (RALS) are the commonly employed surgical modalities. Compared to LPT, minimally invasive hysterectomy offers similar oncologic outcomes, shorter length of stay, reduced blood loss, etc, making it a preferred choice for early-stage EC.

While existing studies have compared the efficacy and safety of CLS and RALS for the treatment of early-stage EC, research on their economic evaluation remains relatively scarce（Clarke et al.,2018）. Several studies have reported that RALS may offer similar oncological outcomes with shorter hospital stays and a lower conversion rate to LPT compared to CLS. However, these benefits are often accompanied by higher costs, potentially imposing a significant economic burden on patients.To alleviate the financial burden on patients and their families, a cost-effectiveness analysis of the two minimally invasive surgical approaches is imperative. This study aimed to evaluate the economic feasibility of RALS for early-stage EC compared to CLS from the Chinese societal perspective, ultimately providing patients with a more rational and effective treatment option.

II. Material and Methods

Confidentiality constraints result in a lack of individual patient data reporting in survival curves from Chinese studies, the survival data for this study originated from a retrospective multi-institutional study involving 655 patients with endometrial cancer, which evaluated surgical outcomes and oncologic endpoints among patients undergoing robotic and laparoscopic surgeries（Matsuo et al.,2021）.

The study population met the following criteria: 1) patients with a definitive diagnosis of endometrial cancer confirmed by preoperative endometrial biopsy; 2) cases with clinical stages I-II (according to the 2009 FIGO staging system) determined through preoperative clinical examination and imaging studies; 3) patients who had not received preoperative adjuvant therapies such as radiotherapy or chemotherapy, with surgery as the primary treatment; 4) patients without coexisting malignancies in other sites.

Both the RALS and CLS groups underwent standard staging surgery for EC, encompassing total hysterectomy, bilateral salpingo-oophorectomy, and pelvic and paraaortic lymphadenectomy. To simplify the model, it was assumed that no adjuvant radiotherapy or chemotherapy was administered postoperatively until disease progression. Upon progression, a combination chemotherapy of paclitaxel and carboplatin was initiated, accompanied by best supportive care. To ensure therapeutic efficacy while minimizing subsequent treatment costs, Chinese-produced generic drugs that have passed consistency evaluations were selected for paclitaxel injection and carboplatin injection. Chemotherapy was administered every 3 weeks for a total of 6 times: intravenous paclitaxel at 175 mg/m2 and carboplatin at (CCR+25)*AUC (AUC=5), also intravenous. Regular follow-ups were conducted both postoperatively and post-chemotherapy, with a frequency of every 3 months for the first two cycles, and subsequently every 6 months starting from the third cycle until the completion of the cycle.

A decision-analytic Markov model was constructed by TreeAge Pro 2022 software. The model encompasses three mutually exclusive states: Progression-Free Survival (PFS), Progressive Disease (PD), and Death. The primary evaluation indicators are the cumulative costs associated with the two surgical approaches, Quality-Adjusted Life Years (QALYs), and Incremental Cost-effectiveness Ratio (ICER). A previous study indicated that the incidence of EC among Chinese women peaks in the 50-59 age group , then the entry age for women in the model was assumed to be 54.5 years. With Chinese average life expectancy of 78.6 years as reported by the National Health Commission of the People's Republic of China in 2023, the model was run for 25 years with a 1-year cycle. Figure 1 presents the Markov state transitions and the decision-analytic Markov model. Both costs and utilities underwent half-cycle correction and were discounted at a rate of 5%. Given the absence of a defined threshold for willingness to pay (WTP) in China, the WTP threshold in this study was set at 3 times the per capita GDP of China in 2023 (specifically ¥275,238/QALY) , in accordance with the recommendations outlined by the World Health Organization（Concin et al.,2021）.

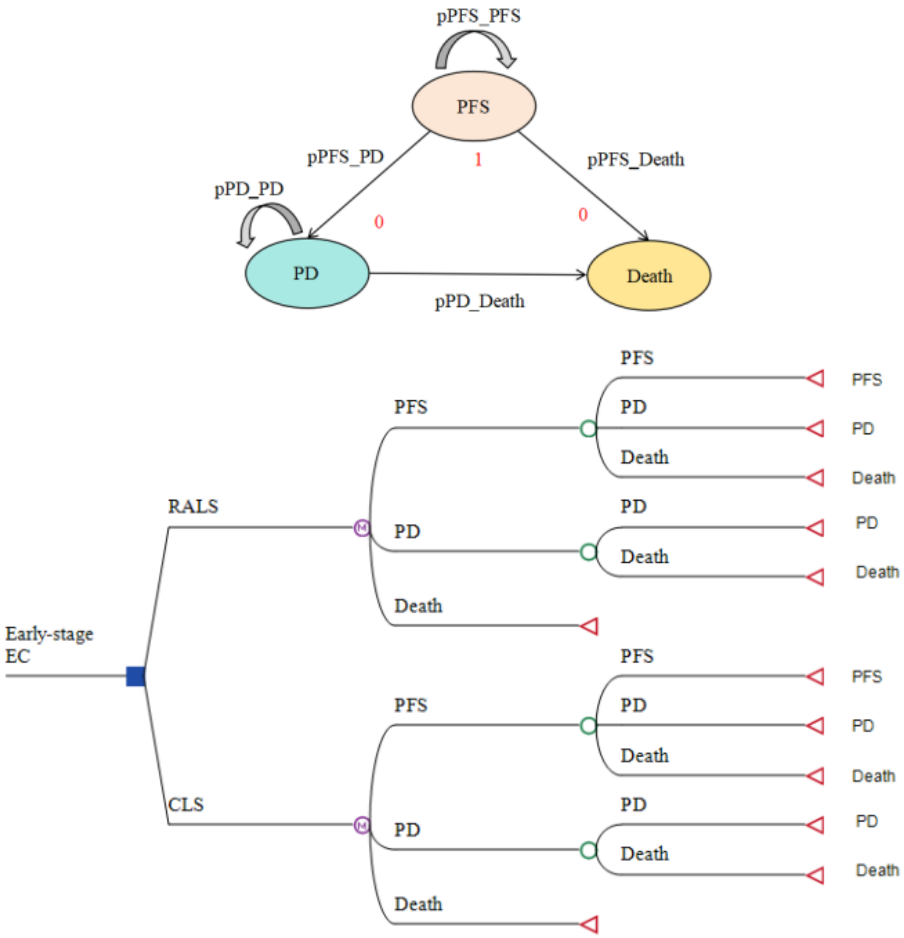

FIGURE 1. A DECISION-ANALYTIC MARKOV MODEL FOR EARLY-STAGE EC

To estimate the state transition probabilities in each cycle more accurately, this study extrapolated the survival curves reported in the retrospective study to obtain survival data beyond the follow-up period. Points were extracted from the survival curves using GetData Graph Digitizer 2.22 software and processed to conform to the data format required for survival analysis. The processed data were then imported into R 4.3.0 software, where the survHE package was utilized to reconstruct individual patient data. These reconstructed data were fitted to various parametric distributions, including Exponential, Gompertz, Weibull, Log-logistic, and Log-normal. The optimal fitting results were determined based on the Akaike

Information Criterion (AIC), Bayesian Information Criterion (BIC), and visual inspection. The fitting results are summarized in Table 1. Exponential distribution was chosen to fit the OS curves, and Log-normal distribution was selected for the PFS curves of both patient groups. The distribution parameters are shown in Table 2, and the curve fitting results are illustrated in Figures 2 and 3. Subsequently, the transition probabilities between the three states were estimated based on the survival functions of fitted PFS and OS curves: 1) The transition probabilities from PFS to PFS were calculated by the following formula: $P_{PFS\_PFS} = S(t+\Delta t)/S(t)$, where $S(t)$ represents the survival function of the fitted PFS curve, and Δt is the duration of the Markov cycle; 2) The transition probability from PFS to death (P_{PFS_Death}) in the first cycle was the cumulative mortality rate, obtained from the OS curve. For cycles beyond the first, the transition probabilities from PFS to death were assumed to be 7.87‰, which is the Chinese natural mortality rate of 2023; 3) Based on the preceding two formulas, the transition probabilities from PFS to PD can be calculated by the following formula: $P_{PFS\_PD} = 1 - P_{PFS\_PFS} - P_{PFS\_Death}$; 4) In order to calculate the transition probabilities from PD to PD, the transition probabilities of survival to survival need to be computed first: $P_{survival\_survival} = S(t+\Delta t)/S(t)$, where $S(t)$ represents the survival function of the fitted OS curve, and Δt is the duration of the Markov cycle, then the transition probabilities from PD to PD were calculated: $P_{PD\_PD} = [(nPFS + nPD) * P_{survival\_survival} - nPFS * P_{PFS\_PFS} - nPFS * P_{PFS\_PD}]/nPD$, where nPFS represents the number of patients in PFS status from the previous cycle, and nPD represents the number of patients in PD status from the previous cycle; 5) Finally, the transition probabilities from PD to death were calculated using the formula: $P_{PD\_Death} = 1 - P_{PD\_PD}$.

TABLE 1 - FITTING RESULTS FOR DIFFERENT PARAMETER DISTRIBUTIONS

KM curves	Exponential	Gompertz	Weibull	Log-logistic	Log-normal
AIC					
RALS_OS	114.3890	115.7383	116.3684	116.2810	115.4137
CLS_OS	254.0846	255.7237	253.7681	253.5278	251.8007
RALS_PFS	268.9517	261.5534	259.3335	259.5007	258.3361
CLS_PFS	498.6598	499.5479	496.8583	496.3280	494.3059
BIC					
RALS_OS	117.9065	122.7732	123.4033	123.3159	122.4486
CLS_OS	258.0909	263.7364	261.7808	261.5405	259.8134
RALS_PFS	272.4691	268.5883	266.3684	266.5356	265.3710
CLS_PFS	502.6661	507.5606	504.8710	504.3407	502.3186

TABLE 2 - DISTRIBUTION PARAMETERS OF SURVIVAL CURVES

KM curves	Optimal fitting distribution	Parameter
RALS_OS	Exponential	rate=0.000886894
CLS_OS	Exponential	rate=0.00103057
RALS_PFS	Log-normal	meanlog=5.041206; sdlog=0.991065
CLS_PFS	Log-normal	meanlog=5.72101; sdlog=1.48265

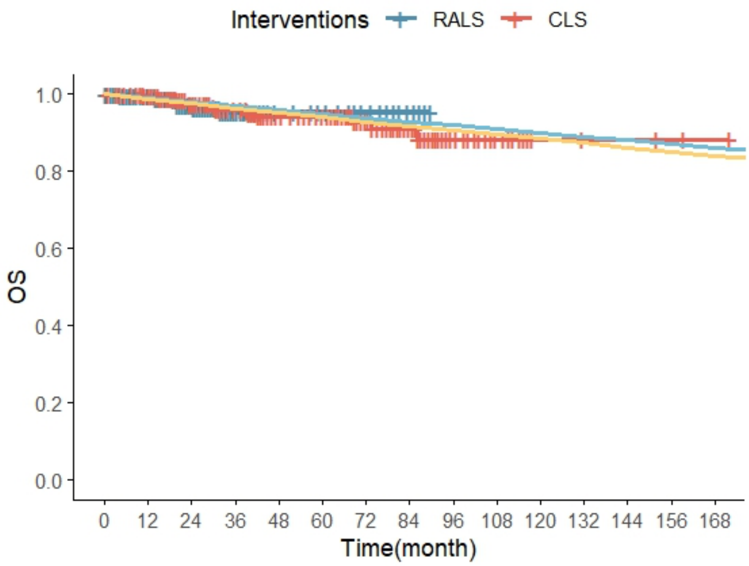

FIGURE 2. OPTIMAL FITTING EXTRAPOLATION RESULTS OF OS CURVES FOR TWO SURGERIES

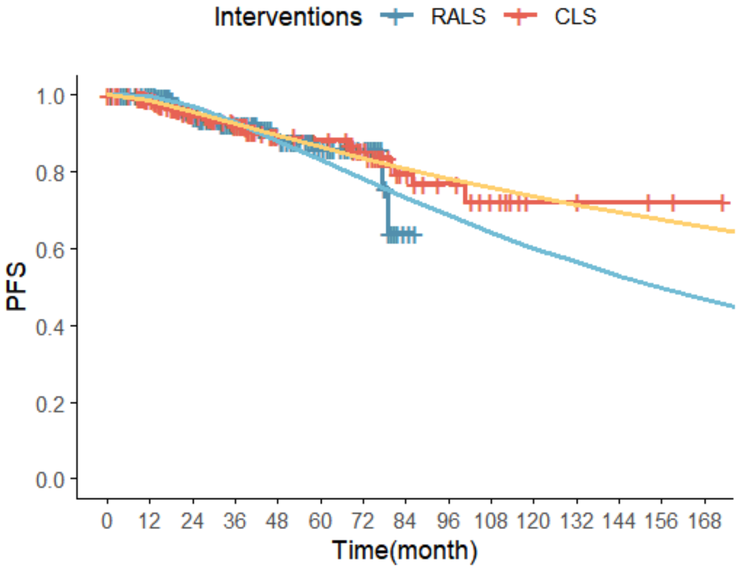

FIGURE 3. OPTIMAL FITTING EXTRAPOLATION RESULTS OF PFS CURVES FOR TWO SURGERIES

The estimation of costs was carried out from a societal perspective, focusing on direct medical costs and indirect costs, excluding direct non-medical costs due to data availability constraints like transportation expenses（Janda et al.,2017）. Some data, such as health utility values, are derived from published literature. Direct medical costs encompass operation costs, the acquisition and maintenance costs of robotic equipment, the costs of specialized consumables for Endowrist, operating room costs, and costs associated with chemotherapy in recurrence and metastasis phases, etc. Within the context of the model, it is hypothesized that adverse events of grade ≥ 3, attributable to chemotherapy, occur only once within each cycle. Regarding indirect costs, this study solely factored in the productivity loss incurred by family members accompanying patients during medical treatment, assuming at least one family member accompanies each patient. As the majority of women in China retire around the age of 55, the productivity loss of patients themselves was not considered in the analysis. The productivity loss was estimated using hospitalization duration and the 2023 Chinese per capita daily disposable income. To account for the time value of money, costs are adjusted to 2023 values based on the survey years of literature data and the Chinese Consumer Price Index (CPI).

TABLE 3- COST AND UTILITY PARAMETERS OF DECISION-ANALYTIC MARKOV MODEL MODEL

Parameter	Base Value	SD	Range	Distribution
Direct costs				
Operation costs (¥)				
Standard staging surgery [a]	2,565.00	261.73	2,052.00-3,078.00	Gamma
Additional charge (with laparoscopy) [b]	200.00	20.41	160.00-240.00	Gamma
Robotic equipment (¥)				
Purchase_IS4000 [c]	26,388,200.00	1,675,487.75	23,998,000.00-27,998,000.00	Gamma
Maintenance/year [c]	1,867,428.57	158,859.74	1,530,000.00-1,980,000.00	Gamma
Consumables _Endowrist	19,929.78	2,033.65	15,943.82-23,915.74	Gamma
Operating room costs (¥/hour)				
Construction costs	1,211.74	154.56	908.81-1,514.68	Gamma
Inventory costs [d]	4,164.72	531.21	3,123.54-5,205.90	Gamma
Personnel costs [e]	3,105.73	396.14	2,329.30-3,882.16	Gamma
Overhead costs [f]	1,639.41	209.11	1,229.56-2,049.26	Gamma
Operative time (hour)				
RALS	4.54	2.72	3.63-5.45	Normal
LPS	3.84	2.27	3.07-4.61	Normal
Depreciable life of robotic equipment	8.00	1.28	5.00-10.00	Normal
Annual operation volume_RALS	250.00	229.59	100.00-1000.00	Normal
Inpatient diagnostic fee (¥/day)	25.00	2.55	20.00-30.00	Gamma
Ward fee (¥/day)	47.00	4.80	37.60-56.40	Gamma
Nursing fee (Grade 2, ¥/day)	12.00	1.22	9.60-14.40	Gamma
Drug costs _chemotherapy				
Carboplatin (10ml:100mg)	51.60	5.27	41.28-61.92	Gamma
Paclitaxel (5ml:30mg)	67.23	6.86	53.78-80.68	Gamma
Best supportive care per time	1,253.44	127.92	1,002.72-1,504.15	Gamma
Routine follow-up per time	507.07	51.73	405.68-608.46	Gamma
Laboratory tests and radiological examinations	2,457.90	250.81	1,966.31-2,949.50	Gamma
≥ Grade 3 AEs costs				
Anemia	2,315.45	236.29	1,852.33-2,778.57	Gamma
Neutropenia	3,124.55	318.83	2,499.65-3,749.45	Gamma
Neutrophil count decreased	3,124.55	318.83	2,499.65-3,749.45	Gamma
White-cell count decreased	1,450.30	147.99	1,160.24-1,740.35	Gamma
Indirect costs				
Length of stay/Sick leave (day)				
RALS	11.59	3.58	9.27-13.91	Normal
CLS	11.89	5.37	9.51-14.27	Normal
Per capita disposable income (¥/day)	107.45	10.96	85.96-128.94	Gamma
Others				
Body surface area (m^2)	1.69	0.17	1.35-2.03	Normal
Weight (Kg)	59.00	6.02	47.20-70.80	Normal
Discount rate	0.05	0.02	0.00-0.08	Beta
Creatinine clearance rate (ml/min)	70.00	7.14	56.00-84.00	Gamma
Utility value				
PFS				
RALS	0.87	0.09	0.70-1.00	Beta
CLS	0.75	0.02	0.60-0.90	Beta

PD	0.63	0.06	0.60-0.90	Beta

III. Results

The results of base-case analysis are presented in Table 4. The cumulative costs for the CLS group and the RALS group were ¥732,822.83 and ¥1,163,581.06, respectively. In comparison to the CLS group, patients in the RALS group gained 1.03 more QALYs at an additional cost of ¥430,758.23, and the derived ICER was ¥417,201.84/QALY, exceeding the predefined WTP threshold (¥275,238/QALY). The results suggested that RALS does not demonstrate superior cost-effectiveness compared to CLS in the management of early-stage EC.

TABLE 4 -THE RESULTS OF BASE-CASE ANALYSIS

Outcome indicators	CLS	RALS
Cumulative costs (¥)	732,822.83	1,163,581.06
Incremental costs (¥)	-	430,758.23
Cumulative effectiveness (QALYs)	9.42	10.45
Incremental effectiveness (QALYs)	-	1.03
ICER (¥/QALY)	-	417,201.84

The tornado diagram (Figure 4) identifies six most influential variables of model outcomes: annual operation volume for RALS, operative time for RALS, operative time for CLS, utility value of PD, depreciable life of robotic equipment, and the costs of consumables for Endowrist. The model exhibited limited sensitivity to variations in other parameters, including the acquisition and maintenance costs of robotic equipment, the discount rate, and the length of hospital stays for both groups, indicating that these factors had minor impacts on the overall outcomes.

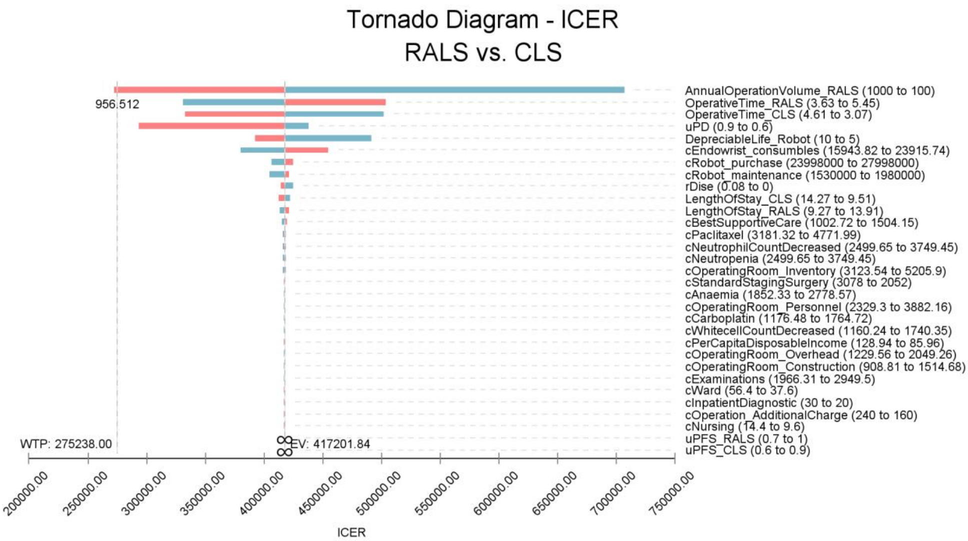

FIGURE 4. TORNADO DIAGRAM OF UNIVARIATE SENSITIVITY ANALYSIS

Upon further examination of the model, we observed a decrease in the ICER value between the RALS and CLS groups as the annual operation volume in the RALS group escalated, approaching the preset WTP threshold. When the annual operation volume per robotic device reaches 947 cases, RALS will emerge as a more cost-effective surgical strategy. This also indicated that with an increase in annual operation volume, the likelihood of the RALS group being cost-effective increased.

TABLE 5-UNIVARIATE SENSITIVITY ANALYSIS (ANNUAL OPERATION VOLUME)

Outcome indicators	CLS	RALS		
		100	550	1000
Cumulative costs (¥)	732,822.83	1,462,322.35	1,054,947.86	1,014,210.41
Incremental costs (¥)	-	729,499.52	322,125.03	281,387.58
Cumulative effectiveness (QALYs)	9.42	10.45	10.45	10.45
Incremental effectiveness (QALYs)	-	1.03	1.03	1.03
ICER (¥/QALY)	-	706,541.44	311,987.44	272,532.04

Abbreviations: RALS, Robot-assisted laparoscopic surgery; CLS, Conventional laparoscopic surgery; QALYs, Quality-adjusted life years; ICER, Incremental cost-effectiveness ratio.

TABLE 6-THRESHOLD ANALYSIS

Variable	Baseline	ICER (¥/QALY)	WTP (¥/QALY)	Threshold
Annual operation volume_RALS	250	155769.06	275,238.00	946.87

Abbreviations: RALS, Robot-assisted laparoscopic surgery; QALY, Quality-adjusted life year; ICER, Incremental cost-effectiveness ratio; WTP, willingness-to-pay.

The ICER scatterplot (Figure 5) presents outcomes from 1000 Monte Carlo simulations. A substantial proportion of the simulated ICER values lie within the 95% confidence interval, underscoring the stability of the analysis. Notably, 43.1% of the simulated ICERs fall below the WTP threshold (¥275,238/QALY), indicating a 43.1% probability that RALS is more cost-effective.

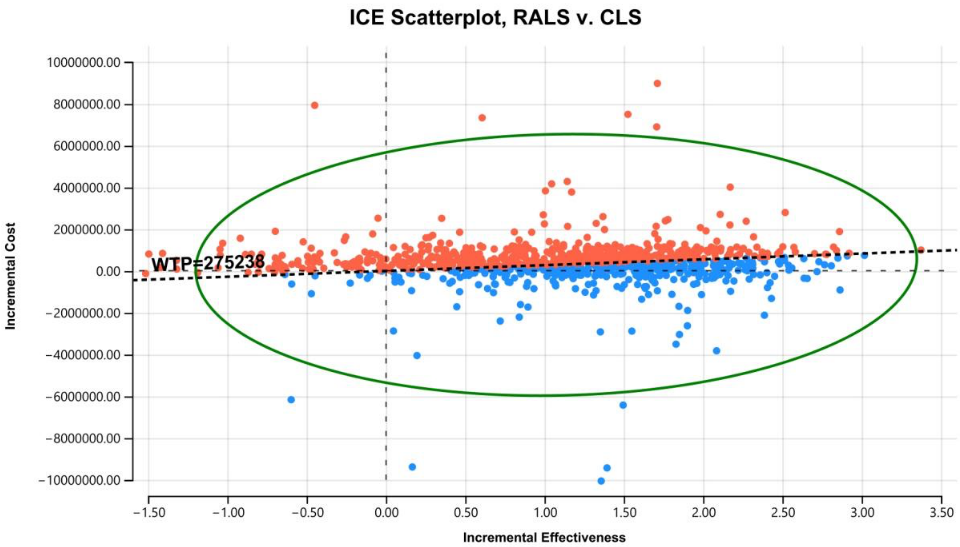

FIGURE 5. THE ICER SCATTERPLOT

Furthermore, Figure 6 presents the cost-effectiveness acceptability curve. As the WTP threshold increases, the probability of cost-effectiveness for RALS also rises. Notably, at a WTP of ¥357,809.40/QALY, both RALS and CLS have an equal probability of being cost-effective. Beyond this threshold, the probability of cost-effectiveness for RALS becomes increasingly favorable, highlighting its potential economic superiority over CLS under higher WTP scenarios.

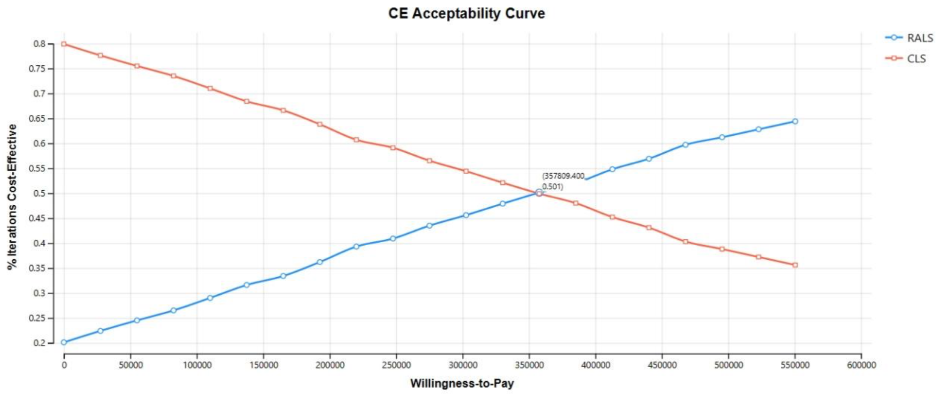

FIGURE 6. THE COST-EFFECTIVENESS ACCEPTABILITY CURVES

IV. Discussion

The findings from both the base-case and sensitivity analyses of this study consistently demonstrated that, in comparison to CLS, RALS does not exhibit cost-effectiveness for the treatment of early-stage EC. The analysis indicated that despite generating superior health outcomes, RALS necessitates greater resource utilization and incurs higher costs compared to CLS. However, an increase in either the annual operation volume conducted by each robot or the WTP threshold would augment the potential of RALS to be cost-effective.

In recent years, fueled by national policies, population aging, and technological advancements, Chinese laparoscopic surgical robotics industry has experienced rapid growth, with notable enterprises such as MedBot, Edge Medical, and Beijing Surgerii emerging, whose products have successively gained market approval or entered clinical trials. Last year, the first China-made Da Vinci Xi Surgical System (IntuitiveFosun, IS4000CN) was launched, signifying the official localization of the globally renowned Da Vinci surgical robot in China. Subsequently, on December 1, 2023, the successful bid for the first China-made Da Vinci IS4000CN was announced, with a winning price of ¥19,780,000. The acquisition cost of robotic equipment has been greatly reduced. If notable advancements can be made in reducing maintenance and specialized consumable costs, RALS may tend to be an even more economically attractive treatment option. Despite the emergence of the IS4000CN, there remains a lack of empirical evidence regarding its clinical performance. Therefore, future research endeavors are imperative to systematically investigate and elucidate any potential differences in clinical outcomes between the Chinese-made Da Vinci and those produced by Intuitive Surgical. Such studies would not only contribute to the advancement of surgical robotics but also inform clinical decision-making and enhance patient care.

From a Chinese societal perspective, our study assessed the cost-effectiveness of RALS and CLS for early-stage EC treatment through a decision-analytic Markov model. Nonetheless, this study has certain limitations. Firstly, there are limitations in data sources. Due to the scarcity of survival data and postoperative quality of life reports specific to the Chinese population, relevant studies from other countries were referenced in calculating the transition probabilities among health states and determining the utility values of each state, potentially introducing bias into the research outcomes. This underscores the need for Chinese researchers to conduct more clinical studies on early-stage EC surgeries tailored to the local population in the future, thereby refining survival analyses and enriching foundational data. Secondly, to simplify the model structure, this study assumed that chemotherapy combined with optimal supportive care would be administered during the postoperative disease progression phase, which may diverge from the choices made by patients and clinicians in actual medical practice.

V. Conclusions

From the Chinese societal perspective, at a WTP threshold of ¥275,238 per QALY, RALS is unlikely to be a cost-effective treatment option for advanced EC compared to CLS. RALS can become cost-effective at an annual operation volume of 947 cases or with an increased WTP threshold. Therefore, policymakers and healthcare providers should consider these factors when evaluating the implementation of RALS in clinical practice, particularly in regions where the annual surgical volume is high or where there is a greater societal willingness to invest in health.

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机器人手术是否有助于降低胰腺恶性肿瘤的疾病经济负担？一项微观成本研究

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摘　要 本研究聚焦于机器人手术对胰腺恶性肿瘤疾病经济负担的影响，属微观成本研究范畴。自1994年腹腔镜胰十二指肠切除术报道后，腹腔镜或机器人辅助技术于胰腺外科的应用备受关注，其在胰腺癌根治治疗的肿瘤学效果与手术安全性存争议，且机器人手术的经济学收益不明。研究经医院病案首页与手术记录获取患者基本、手术、病理分期、费用等信息；同时通过调查问卷收集患者就医期间交通、住宿、营养、时间成本等。本阶段清理完成了手术时间、患病部位变量。机器人手术患者的平均手术持续时间相对其他术式更短；行机器人、腹腔镜和开腹手术者中，患病部位均以胰尾占比最高，分别为54.7%、75.8%和57.1%。本次还统计了患者出院时及出院后90天的院外成本数据，患者总体时间成本6346元；家属总体时间成本11612元; 例均交通费5134元，患者住宿费2982元，家属住宿、陪床费2388元，患者营养费660元；机器人手术患者和家属的时间成本更少。已经完成4713例病例的院内费用数据收集，105例出院时的院外数据收集，和75例出院后90天的院外数据收集。

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一、背景

1994 年世界首例腹腔镜胰十二指肠切除术（laparoscopic pancreatoduodenectomy，LPD）被报道以来，腹腔镜或机器人辅助技术应用于胰腺外科的探索一直在进行(Shah and Singh 2024)。当前，腹腔镜或机器人辅助手术应用于胰腺癌根治性治疗方面的争议焦点主要集中于治疗效果的肿瘤学评价与手术安全性等方面。关于腹腔镜或机器人辅助胰腺癌根治术，中国专家在 2022 年版的共识中讨论了其疗效和安全性，认为微创根治术具有广阔的应用前景(Study Group of Minimally Invasive Treatment for Pancreatic Cancer in China Anti-Cancer Association and Chinese Pancreatic Surgery Association 2023)。机器人手术费用高昂，但患者恢复快、并发症少，其经济学收益与传统术式相比尚无定论。

本次进展分为两个部分，一是汇报数据清理的具体细节及结果；二是汇报数据获取情况。

二、方法

通过医院病案首页、手术记录信息，我们获取了患者基本特征、手术信息、病理分期、费用信息，具体变量包括性别、年龄、婚姻状况、通讯地址、入院日期、入院科室、出院日期、主要诊断、治疗结果、主诊医生、医保类型（城镇职工/城乡居民/非医保）、手术日期、手术开始时间、手术结束时间、手术类型、手术名称、术中出血量、并发症、病理分期、总费用、床位费、护理费、西药费、放射费、输血费、诊察费、手术费、检验费等变量。通过问卷调查方式，我们获取了直接非医疗费用，包括交通、住宿、营养费用，以及间接成本，包括患者和家属因误工造成的经济损失。

依据获取数据中的手术开始时间和手术结束时间计算，将所有时间标化成：24 时制，以时为单位，进行运算。手术持续时间（时）=手术结束时间（时）-手术开始时间（时）。

依据病理分期中的文字描述，提取相关关键词获取主要患病部位信息。主要患病部位包括：胰头、胰颈、胰体、胰尾、全胰。

由于病理分期项中的文字信息未规范和标化，主要依据病理分期中出现以下关键词进行信息提取：（1）胰尾：病理胰尾、胰体尾、胰腺尾、胰腺体尾部、胰腺主胰管黏液性囊腺肿瘤、胰腺（体尾、体尾部、体尾、胰腺（尾、胰（尾、尾部；（2）胰头：胰头、胰头部、胰腺头部、胰腺钩突部；（3）胰颈：颈部、胰腺颈部、胰颈、胰腺中段、中段；（4）胰体：胰腺体部等。（5）全胰：病理分期中未出现（1）、（2）、（3）、（4）中关键词，或直接描述胰腺病变的，具体进行人工判断。

拟描述胰腺癌的 TNM 分期信息，目前提取的病理分期信息较难提取 TNM 信息或信息不全，且需进行人工判断 TNM 分期，需进一步尝试从病案首页中直接调取标准化的 TNM 分期信息。

胰腺癌 TNM 分期的意义如下：

• 肿瘤的大小(T)

• 癌细胞是否扩散到癌症附近的淋巴结(N)

• 肿瘤是否已转移到体内的其它地方(M)，医生把已转移的癌症称为继发性癌症或转移性癌症。

TNM 系统用于世界各地的癌症分期。医生使用同一个分期系统很重要，因为他们在谈论同一疾病时可以进行比较。

肿瘤的大小(T)分为 5 个阶段：

• Tis(原位癌)是非常早期阶段的胰腺癌，还没有机会扩散，这种类型的癌症很少见。

• T1 是指胰腺内的肿瘤，不大于 2 厘米

• T2 是指肿瘤是仍在胰腺内，不管从任何方向测量都大于 2 厘米

• T3 是指癌症已开始侵入胰腺周围的组织，但它还没有侵入附近的大血管

• T4 意味着癌症已进一步扩散到胰腺远处的组织或器官，并且侵入到附近的大血管

肿瘤的淋巴结(N)分期：

• N0 意味着淋巴结中没有癌症细胞

• N1 意味着有淋巴结含有癌细胞，所以癌症更有可能扩散到胰腺以外

肿瘤的 M 分期：

• M0 指癌症没有转移到远处器官如肝或肺部

• M1 是指癌症已转移至其它器官

三、结果

（一）数据清理结果

一、住院数据变量清理

1、手术持续时间（时）

已经清理完成1730名病例的院内数据，其中完整汇报了手术时间的99.54%（1722/1730）；平均手术持续时间5.8小时（标准差1.80）。行机器人手术者972例（包括机器人+腹腔镜、机器人+开腹），平均手术持续时间5.62小时（标准差1.69）；腹腔镜手术者148例（包括腹腔镜+开腹），平均手术持续时间6.54小时（标准差1.85）；开腹手术者工495例，平均手术持续时间5.92小时（标准差1.89）。不同手术类型患者的手术持续时间、患病部位如表1所示，机器人手术患者的平均手术持续时间相对其他术式更短。

表 1. 不同手术类型患者的手术持续时间（时）

手术类型	手术持续时间（时）（均值±标准差）
腹腔镜（包括腹腔镜+开腹）	6.54±1.85

机器人（包括机器人+腹腔镜、机器人+开腹）	5.62±1.69
开腹	5.92±1.89
总计	5.80±1.80

2、患病部位信息

已经清理完成1730名病例的院内数据，可提取患病部位信息93.99%（1626/1730），其中0.18%（3/1626）主要患病部位非胰腺。在1623例主要患病部位为胰腺的病例中，胰尾占比最高57.7%（936/1623）,其次是全胰26.4%（429/1623）和胰头11.8%（191/1623）(见表2）。不同手术类型患者中，行机器人手术者（包括机器人+腹腔镜、机器人+开腹）、腹腔镜手术者（包括腹腔镜+开腹）和开腹手术者中，患病部位均以胰尾占比最高，分别为54.7%、75.8%和57.1%（表1）。

表2. 患病部位信息

患病部位	总体	腹腔镜（包括腹腔镜+开腹）	机器人（包括机器人+腹腔镜、机器人+开腹）	开腹
全胰	429（26.4%）	24（16.1%）	301（31.0%）	103（20.4%）
胰颈	27（1.7%）	0	13（1.3%）	14（2.8%）
胰颈+胰体	4（0.2%）	0	2（0.2%）	2（0.4%）
胰颈+胰体+胰尾	8（0.5%）	1（0.7%）	4（0.4%）	3（0.6%）
胰体	23（1.4%）	1（0.7%）	9（0.9%）	13（2.6%）
胰头	191（11.8%）	10（6.7%）	110（11.3%）	71（14.1%）
胰头+胰颈+胰体	1（0.1%）	0	0	1（0.2%）
胰尾	936（57.7%）	113（75.8%）	531（54.7%）	288（57.1%）
胰尾+胰头	2（0.1%）	0	0	2（0.4%）
胰尾+胰头+胰颈	2（0.1%）	0	0	2（0.4%）

二、院外随访数据清理

已经清理完成75名病例的院外数据（出院时+90天随访），患者总体时间成本6346元；家属总体时间成本11612元; 例均交通费5134元，患者住宿费2982元，家属住宿、陪床费2388元，患者营养费660元。不同手术类型患者的例均非医疗费用和间接成本如表3所示，机器人手术患者和家属的时间成本更少。

表3. 不同手术类型患者的例均非医疗费用和间接成本（元）

出院90天	854	57	378	90	979	3074

（二）研究数据获取进度

1.通过问卷调查方法获取直接非医疗成本和间接成本，目前已完成105名患者出院时的费用收集，以及75名患者出院后90天的费用信息收集。

2.通过院内数据抄录方式获取医疗成本，目前已根据术式关键词在医院系统中共筛选出12166例于2014.1.1-2024.9.12接受了机器人/腹腔镜/开腹胰腺切除术的患者，结合诊断，进一步筛选其中的胰腺恶性肿瘤病例4713例，未来将继续筛选诊断为壶腹部位恶性肿瘤的患者中确诊为胰腺恶性肿瘤的病例。目前已完成4713例胰腺恶性肿瘤患者的信息抄录。

手术类型		交通费	家属住宿、陪床费	患者住宿费	患者营养费	患者时间成本	家属时间成本
腹腔镜	总体	4382	920	657	270	8396	15595
	出院时	3560	920	590	270	7384	13265
	出院90天	822	0	67	0	1012	2330
机器人	总体	4752	2298	3535	811	5593	10622
	出院时	4038	2283	3017	796	4796	7892
	出院90天	714	15	518	15	797	2730
开腹	总体	6150	3189	3007	550	6813	11680
	出院时	5037	3031	2725	287	5531	7661
	出院90天	1113	158	282	263	1282	4019
总计	总体	5134	2388	2982	660	6346	11612
	出院时	4280	2331	2604	570	5367	8538

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基于真实世界数据的机器人辅助粗隆间骨折手术的卫生经济学评估

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一、背景

随着人口老龄化，骨质疏松患者的数量正在增加 (Curry SJ et al.，2018)。髋部骨折（HF）作为骨质疏松最严重的并发症，预计到 2050 年将增加至 450 万例，其中约一半的新发病例可能发生在亚洲 (Troels MJ et al.，2024)。髋部骨折对医疗系统造成了沉重的负担，美国每年约需花费 60 亿美元 (Tajeu GS et al.，2024)。髋部骨折与更高的死亡率、残疾风险和再住院率相关，其中粗隆间骨折约占 45%，其 1 年死亡率约为 14%至 36%，而 20%的骨折患者需要长期护理 (Bhandari M et al.，2019；Thach T et al.，2022)。

近年来，随着技术的进步和生产成本的降低，手术机器人的在骨科领域得到飞速发展。手术机器人能够提供为术者提供手术规划模拟、导航及微创精确定位操作等功能，有效提高骨科手术的操作质量，减少术中风险 (Kayani B et al.，2018). 在股骨粗隆间骨折的治疗中，闭合复位髓内钉内固定术因其微创性和良好的生物力学特性被视为首选术式。精确的内固定螺钉置入对于维持骨折端稳定性、促进骨愈合以及降低术后并发症风险具有关键作用。其中，理想入钉点的准确定位是手术成功的重要技术要点，其直接影响以下几个方面：1）维持骨折解剖对位；2）避免内固定物周围再骨折；3）最小化对臀中肌的医源性损伤 (Kaplan K et al.，2008)。因此，术中对入钉点的精准选择和定位是确保手术疗效、减少相关并发症的核心操作环节。AI-Naseem 等人的 meta 分析指出与传统手术相比，机器人辅助下进行置钉操作显著减少术中出血量、导针穿入次数和射线暴露时间，提高了螺钉位置的精准度，但两组在手术时间方面无显著差异 (Al-Naseem et al.，2022)。Lan 等报道，机器人辅助定位粗隆间骨折近端进针点，研究结果表明：与传统手术方法相比，机器人辅助手术够显著减少手术

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时间、术中透视的次数、术中患者失血量和术中导针插入次数，提高导针“一次插入”的成功率。

二、研究方法

开展真实世界研究，回顾性收集 2019 年 1 月至 2021 年 12 月期间所有 60 岁及以上经诊断为粗隆间骨折的患者。排除标准包括：既往髋部骨折史、数据缺失（含治疗方案、住院费用等关键信息）。我们从每份病历中提取以下数据：性别、年龄、合并症、输血情况、ICU 入住记录、麻醉方式、住院时长、医院等级与类型、住院费用及因二次骨折再入院信息。死亡数据来源于北京市疾病预防控制中心数据库，并与住院记录中的患者唯一编码进行匹配，同时提取具体死亡日期及死因。

研究基于 TreeAge Pro 软件构建马尔可夫模型，用于估算 3 年内的治疗总成本和质量调整生命年（QALYs）。通过成本效益分析，我们计算了增量成本效益比（ICER），即将传统髓内钉置入手术、传统髓外固定手术、机器人辅助髓内钉置入手术与保守治疗之间进行比较，每获得一个 QALY 或延长单位生存时间所增加的额外成本，从而确定最具成本效益的治疗方案。

三、研究结果

经纳入、排除标准筛选后，共有 16238 例患者被纳入本研究，根据手术方式分为传统髓内治疗组 (7896 例)，传统髓外治疗组 (5,447 例)，机器人辅助髓内置入组 (608 例) 和保守治疗组 (2287 例)。

研究结果显示，机器人辅助置钉的使用导致了治疗成本的增加。与 2019 年相比，2021 年股骨粗隆间骨折患者的治疗费用中位数增长了 4,884.9 美元（增幅 52.9%）[从 9,230.6 美元（四分位距：4,649.7-12,252.0 美元）增至 14,115.5 美元（四分位距：9,862.4-18,332.7 美元）]，而同期保守治疗的人均费用仅增加 382.6 美元[从 1,879.6 美元（四分位距：733.1-5,691.2 美元）增至 2,262.6 美元（四分位距：1,055.4-5,414.9 美元）]。机器人辅助手术患者的治疗费用中位数较传统置钉患者高出 1,223.8 美元（增幅 9.5%）[14,086.0 美元（四分位距：11,695.4-17,230.9 美元）vs. 12,862.2 美元（四分位距：9,600.6-16,716.0 美元）]。

研究进一步比较了三种手术方式相对于保守治疗的增量成本和增量 QALYs。结果显示，传统髓内置钉获得的质量调整生命年（QALYs）最高，其次为传统髓外治疗、机器人辅助手术和保守治疗（表 1）。根据支付意愿（WTP）阈值分析，图 1 表明传统髓内置钉是最具成本效益的治疗策略。在成本效益边界分析中，传统髓内置钉的成本效益最优（ICER=每提高 1%生存率需 1,273.48 美元，每获得 1 个 QALYs 需 31,354.20 美元），其次是机器人辅助手术（每提高 1%生存率需 2,249.25 美元，每获得 1 个 QALYs 需 45,406.31 美元）和传统髓外治疗（每提高 1%生存率需 3,879.61 美元，每获得 1 个 QALYs 需 51,679.28 美元）。

表1. 2019至2021年粗隆间骨折不同治疗方式之间的成本-效果分析

	Robotic-assisted intramedullary surgery	Intramedullary implants	Extramedullary implants	Conservative treatment
Costs per person	52082.1 ($14086.0)	45170.9 ($12862.2)	50488.3 ($14191.8)	7792.8 ($2165.0)
Effectiveness				
Total QALYs per person	1.889	1.945	1.905	1.683
1 year	0.661	0.672	0.663	0.617
2 year	0.625	0.645	0.630	0.544
3 year	0.603	0.628	0.612	0.522
ICER				
△Costs/△QALYs	$45406.31	$31354.20	$51679.28	Ref

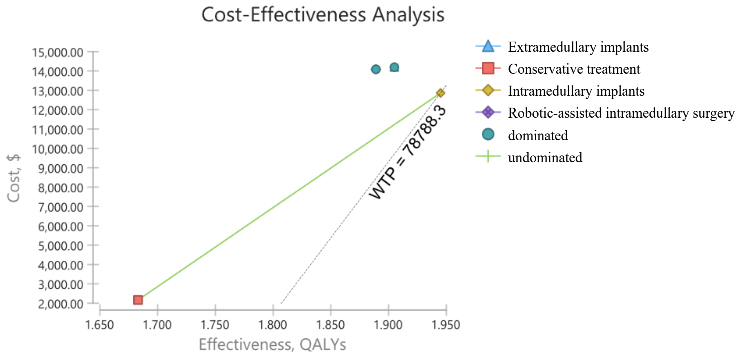

图 1. 粗隆间骨折不同手术策略的成本效益分析

四、研究结论

2019 至 2021 年间，机器人开始应用于粗隆间骨折的辅助置钉，但应用量较少，且并未在减少患者术后死亡及二次骨折骨折风险发现显著收益，也为能显著增加患者术后的质量寿命调整年。且由于整体手术费用较高，并未显示出良好的成本-效益。其原因可能是机器人初步应用于临床，手术技术尚不成熟，研究下一步拟继续扩大样本，纳入 2021 至 2024 年的人群，同时扩大骨科手术范围，纳入关节置换和脊柱手术患者。

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骨科手术机器人辅助手术与传统手术的临床疗效与卫生经济学研究：一项多中心、观察性、回顾性队列研究

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摘 要 手术机器人的出现，可有效缩短外科医生微创手术学习曲线，提高外科医生学习效率及培训质量。本研究旨在通过真实世界数据，开展回顾性队列研究，评价手术机器人辅助手术与传统手术的学习曲线差别、临床疗效差异，并进行卫生经济学分析。研究将对传统手术组和机器人手术组医生的置钉准确性进行分析，并对并发症发生情况、手术时间、患者功能评分情况、治疗费用等次要指标进行比较分析。

一、引言

骨科手术机器人是机器人在临床应用领域的一个重要分支，起源于20世纪90年代初。以脊柱手术机器人为例，世界上第一个机器人脊柱手术平台（Robtic Spine System，RSS）于2004年获得美国食品和药品监督管理局（Food and Drug Administration，FDA）批准（D'Souza M et al, 2019），此后机器人辅助放置胸腰椎椎弓根螺钉得到了广泛的研究。天玑骨科机器人（北京天智航医疗科技股份有限公司，中国）是我国自主研发设计并通过中国FDA审批的第一个国产骨科手术机器人，并于2015年成功完成了世界首例骨科手术机器人导航下的颈椎内固定手术，并可辅助多种部位包括脊柱与四肢关节等部位的手术 (Tian et al, 2017)。

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手术机器人可以在术前进行手术规划，模拟手术过程，以及实现术中导航定位，执行手术规划(Bao et al, 2024)。目前机器人辅助置钉是脊柱外科领域最成熟的应用场景，与传统置钉比较具有更好的准确性及安全性，可有效减少手术并发症，减少医患双方的 X 线辐射暴露，减少创伤，缩短手术时间 (Caelers et al, 2023)。

为准确评价骨科手术医生的培训过程与质量，使用手术曲线进行评价是一个较为成熟的评价体系 (Akazawa et al, 2024)。一般而言，手术时间，住院时间以及并发症率是评估是否度过学习曲线的三个最常用参数 (Soomro et al, 2020)。这也是众多研究中外科医生们较为关注的，衡量手术是否有效率，手术结果是否令人满意的重要结果。本研究将采用真实世界研究设计，开展回顾性队列研究，评价手术机器人辅助手术与传统手术的学习曲线差别、临床疗效差异，并进行相应的卫生经济学分析。项目的实施，将有助于有效评价手术机器人与传统手术的临床疗效与经济效应差异，揭示骨科手术机器人的潜在优势，为医疗决策者、临床医生、医疗器械商、患者、医保决策者提供重要的研究结论，为未来的医疗实践和政策制定提供重要的参考依据，更好地满足老龄化社会中不断增长的骨科相关医疗需求。

二、方法

（一）研究设计

研究采用多中心、观察性、回顾性队列研究设计。牵头单位为中山大学附属第三医院，参与单位包括北京积水潭医院等医院。

（二）研究对象

因腰椎间盘突出症、腰椎滑脱症、腰椎椎管狭窄症、腰椎退行性侧凸、胸腰椎骨折等疾病，或因四肢关节其他部位需行手术、在参与单位骨科住院或门诊就诊的患者。预计招募 20 名医生及其实施手术的患者，患者人数总计 600 名。

（三）研究方案

招募脊柱外科医生，对符合入组标准且同意参与研究的医生进行知情同意，回顾性收集符合标准的患者资料并进行随访。将纳入的脊柱外科医生分组为传统手术组和手术机器人辅助手术组。

传统手术组采用标准的腰椎手术方式进行学习，由有经验的副主任或主任医师指导医师进行脊柱外科手术过程，包括手术暴露、置钉等基本操作。手术机器人组采用手术机器人进行治疗。由有经验的副主任或主任医师指导医师，使用手术机器人辅助进行脊柱外科手术规划、手术实施过程，完成手术暴露、置钉等基本操作，测量并记录相应指标。

研究的主要结局指标为：传统手术组和机器人组手术医生的置钉准确性差异。采用Gertzbein-Robbins分级标准评价椎弓根螺钉放置的准确性。

研究的次要结局指标包括：并发症发生情况、手术时间、手术出血量、住院时间、患者功能评分情况、再入院情况、手术费用、治疗费用情况等。

（四）统计分析

本研究根据两组收集到的相关数据，采用Stata 18.0和SPSS 19.0软件进行统计分析，计数资料以频率和百分比表示，计量资料以均数±标准差表示（X±S）。对于计量资料，若满足正态分布并且方差齐性，我们将采用双重差分模型（Difference in Difference）、截面回归等计量方法，同时对独立样本 t 检验；若不满足正态分布或方差齐性的要求，我们将采用非参数检验（Nonparametric）方法，如 Mann-Whitney U 检验，以保证分析的准确性和可靠性。对于计数资料，我们将采用卡方检验或 Fisher's 确切性检验。使用Logistic 回归分析法分析基线数据对各组受试者疗效的影响，结果以 OR 值和 95%可信区间表示；以 $P<0.05$ 为差异有统计学意义。在分析过程中，还将充分考虑多重检验的问题，采用适当的校正方法（如 Bonferroni 校正）来控制误差率，以确保结果的可靠性。

此外，我们还将开展亚组分析，探索不同患者子群之间的治疗效果差异，从而为个性化治疗提供有价值的信息。

在处理受试者失访和数据缺失方面，将采取多种策略来确保分析结果的可靠性和准确性。首先，本研究将最大限度地减少受试者失访的发生，通过建立严格的随访机制和提供多种沟通途径，以便及时获取受试者的治疗情况和相关数据。其次，对于出现数据缺失的情况，本研究将采用合适的统计方法进行处理，如多重插补法或敏感性分析，探究缺失数据可能对结果产生的影响，并在分析中进行充分说明。

在数据分析的过程中，对本研究的数据进行整理和分析，通过研究数据的系统分析保证分析结果的客观性和可靠性。本研究将通过多种计量分析方法探究手术机器人与传统手术的临床效应与经济学效应的差异，并通过计量的稳健性检验进一步确保研究结论的科学性和严谨性，根据数据分析结论进一步得出本研究的最终结论，进而对医院、患者等相关主体的医疗决策提供参考。

三、讨论

骨科手术机器人的推广应用，可有效缩短外科医生微创手术学习曲线，提高外科医生学习效率及培训质量，对减少患者手术并发症与不良结局预后与地区间健康不平等具有重要意义。本研究已纳入中山大学附属第三医院、北京积水潭医院等医院开展多中心研究，目前已完成调查问卷编制工作，正在进行所在医疗机构的伦理审批和数据清洗工作。预期项目将在 2025 年下半年取得显著进展，可明确外科医生机器人手术的学习曲线及进行卫生经济学分析，对科学评价手术机器人疗效及成本效益具有重要意义。

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机器人辅助腹腔镜手术与传统腹腔镜手术治疗早期子宫内膜癌的成本效果分析

张敏 浦科学*

摘 要 为了评估机器人辅助腹腔镜手术（RALS）与传统腹腔镜手术（CLS）在早期子宫内膜癌（EC）治疗中的成本效益，本研究从中国社会视角出发，采用终身时间范围进行分析。主要评估指标包括累计成本、质量调整生命年（QALYs）和增量成本效益比（ICER）。结果表明，与CLS 相比，RALS 未显示出更高的成本效益。单变量敏感性分析指出，随着 RALS 的年度手术量增加，ICER 下降。特别是当每台机器人设备的年度手术量达到 947 例时，RALS 将成为更具成本效益的手术策略。概率敏感性分析表明，当支付意愿（WTP）阈值超过¥357,809.40 时，RALS 变得更具成本效益。从中国社会视角来看，在支付意愿阈值为¥275,238/QALY 时，RALS 不太可能成为早期 EC 的成本效益治疗选择。随着年度手术量的增加和支付意愿阈值的提高，RALS 可能变得具有成本效益。

一、引言

子宫内膜癌（EC）是全球女性中第六大常见恶性肿瘤，但在发达国家的妇科癌症中发病率居首位（Bray et al.,2024）。尽管以往研究表明，亚洲人群中子宫内膜癌的发病率相对较低（Katagiri et al.,2023），但近期统计数据显示，2022 年中国新增病例达84,520 例，死亡 17,543 例，中国已成为子宫内膜癌发病率显著较高的地区。大多数子宫内膜癌患者在疾病早期被确诊，此时肿瘤局限于子宫，及时的手术干预等治疗方法已被证明可获得较高的治愈率（Gu, et al.,2021）。

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长期以来，子宫内膜癌的治疗主要依赖手术干预，术后放疗和化疗作为辅助治疗（Wijayabahu et al.,2024）。手术干预是早期子宫内膜癌的首选治疗方法，标准手术方式为全子宫切除加双侧附件切除术。目前，开腹手术（LPT）、传统腹腔镜手术（CLS）和机器人辅助腹腔镜手术（RALS）是常用的手术方式。与开腹手术相比，微创子宫切除术具有相似的肿瘤学结局，且住院时间更短、失血量更少等，因此成为早期子宫内膜癌的首选。

然而在某些情况下，传统腹腔镜下的子宫内膜癌全面分期手术会遇到困难和限制，尤其是在盆腔和腹主动脉旁淋巴结切除术中（Clarke et al.,2018）。与传统腹腔镜相比，机器人手术平台配备 360° 可旋转器械，提供三维手术视野，并能过滤手部震颤，使外科医生能够快速掌握手术技能。目前，机器人手术系统在妇科肿瘤的手术治疗中应用越来越广泛。

尽管已有研究比较了 CLS 和 RALS 治疗早期 EC 的疗效和安全性，但关于它们的经济评价研究相对较少。多项研究报告称，与 CLS 相比，RALS 可能具有相似的肿瘤学结局，且住院时间更短，转为开腹手术的比例更低。然而，这些优势往往伴随着更高的成本，可能给患者带来巨大的经济负担。为减轻患者及其家庭的经济负担，对这两种微创手术方式进行成本-效果分析势在必行。本研究旨在从中国社会角度评估 RALS 相较于 CLS 治疗早期 EC 的经济可行性，最终为患者提供更合理有效的治疗选择。

二、方法

由于保密限制，中国研究中的生存曲线缺乏个体患者数据报告。本研究的生存数据来源于一项回顾性多机构研究，涉及 655 名子宫内膜癌患者，评估了接受机器人和腹腔镜手术患者的手术结果和肿瘤学终点（Matsuo et al., 2021）。研究人群符合以下标准：1）通过术前子宫内膜活检确诊的子宫内膜癌患者；2）根据 2009 年 FIGO 分期系统，通过术前临床检查和影像学研究确定的临床 I-II 期病例；3）未接受术前辅助治疗（如放疗或化疗），以手术为主要治疗手段的患者；4）无其他部位恶性肿瘤的患者。

RALS 和 CLS 组均进行了标准的子宫内膜癌分期手术，包括全子宫切除术、双侧输卵管卵巢切除术以及盆腔和腹主动脉旁淋巴结清扫术。为简化模型，假设术后未进行辅助放疗或化疗，直到疾病进展。疾病进展后，开始使用紫杉醇和卡铂联合化疗，并辅以最佳支持护理。为确保治疗效果并尽量降低后续治疗成本，选择了通过一致性评价的中国生产仿制药用于紫杉醇和卡铂注射。化疗每 3 周进行一次，共进行 6 次：静脉注射紫杉醇 175 mg/m2 和卡铂(CCR+25)AUC (AUC=5)，也为静脉注射。术后和化疗后进行定期随访，前两个周期每 3 个月一次，随后从第三周期开始每 6 个月一次，直到周期结束。

使用 TreeAge Pro 2022 软件构建了一种决策分析马尔科夫模型。该模型包括三个互斥状态：无进展生存期(PFS)、进展期疾病(PD)和死亡。主要评估指标为两种手术方式的累计成本、质量调整生命年(QALYs)和增量成本效益比(ICER)。先前研究表明，中国女性子宫内膜癌的发病率在 50-59 岁年龄组达到峰值，因此模型中女性的进入年龄假定为54.5 岁。根据中华人民共和国国家卫生健康委员会 2023 年报告的中国平均预期寿命为78.6 岁，模型运行 25 年，周期为 1 年。图 1 展示了马尔科夫状态转换和决策分析马尔科夫模型。成本和效用均经过半周期校正，并以 5%的折扣率进行贴现。鉴于中国缺乏明确的支付意愿(WTP)阈值，本研究中的 WTP 阈值设定为 2023 年中国人均 GDP 的 3 倍（具体为¥275,238/QALY），依据世界卫生组织的建议（Concin et al., 2021）。

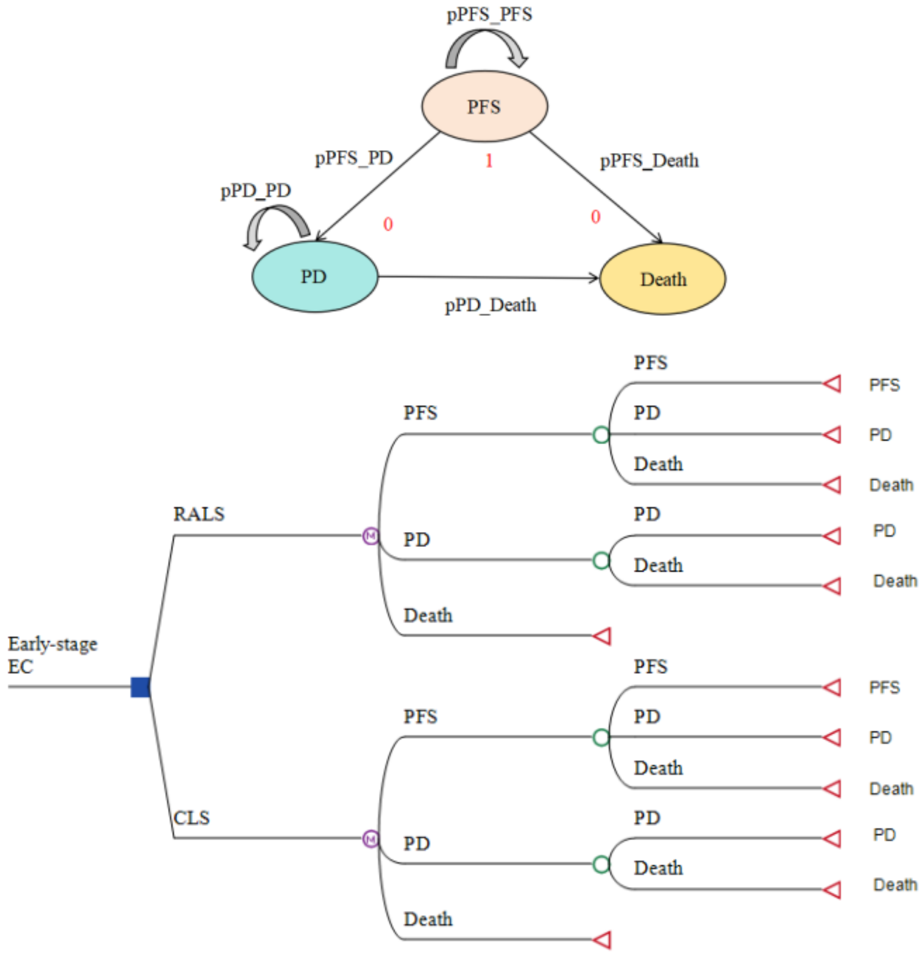

图1.早期子宫内膜癌的决策分析马尔科夫模型

为更准确地估计每个周期的状态转移概率，本研究对回顾性研究中报告的生存曲线进行外推，以获取随访期后的生存数据。使用 GetDataGraphDigitizer2.22 软件从生存曲线中提取数据点，并进行处理以符合生存分析所需的数据格式。然后将处理后的数据导入 R4.3.0 软件，使用 survHE 软件包重建个体患者数据。对这些重建数据进行多种参数分布拟合，包括指数分布、冈珀茨分布、威布尔分布、对数-逻辑分布和对数-正态分布。根据赤池信息准则（AIC）、贝叶斯信息准则（BIC）和直观检查确定最佳拟合结果。

拟合结果总结于表 1。选择指数分布拟合两组患者的总生存期（OS）曲线，对数-正态分布拟合无进展生存期（PFS）曲线。分布参数见表 2，曲线拟合结果见图 2 和图 3。随后，根据拟合的 PFS 和 OS 曲线的生存函数估计三个状态之间的转移概率：1）PFS 到 PFS 的转移概率计算公式为：$P_{PFS\_PFS} = S(t+\Delta t)/S(t)$，其中 $S(t)$ 表示拟合的 PFS 曲线的生存函数，Δt 为马尔可夫周期的持续时间；2）第一周期 PFS 到死亡（P_{PFS_Death}）的转移概率为累积死亡率，从 OS 曲线获取。对于第一周期之后的周期，PFS 到死亡的转移概率假定为 7.87‰，即 2023 年中国自然死亡率；3）根据前两个公式，PFS 到 PD 的转移概率计算公式为：$P_{PFS\_PD} = 1 - P_{PFS\_PFS} - P_{PFS\_Death}$；4）为计算 PD 到 PD 的转移概率，需先计算生存到生存的转移概率：$P_{survival\_survival} = S(t+\Delta t)/S(t)$，其中 $S(t)$ 表示拟合的 OS 曲线的生存函数，Δt 为马尔可夫周期的持续时间，然后计算 PD 到 PD 的转移概率：$P_{PD\_PD} = [(nPFS + nPD) * P_{survival\_survival} - nPFS * P_{PFS\_PFS} - nPFS * P_{PFS\_PD}] / nPD$，其中 nPFS 表示上一周期处于 PFS 状态的患者数量，nPD 表示上一周期处于 PD 状态的患者数量；5）最后，使用公式计算 PD 到死亡的转移概率：$P_{PD\_Death} = 1 - P_{PD\_PD}$。

表1.不同参数分布的拟合结果

KMcurves	Exponential	Gompertz	Weibull	Log-logistic	Log-normal
AIC					
RALS_OS	114.3890	115.7383	116.3684	116.2810	115.4137
CLS_OS	254.0846	255.7237	253.7681	253.5278	251.8007
RALS_PFS	268.9517	261.5534	259.3335	259.5007	258.3361
CLS_PFS	498.6598	499.5479	496.8583	496.3280	494.3059
BIC					
RALS_OS	117.9065	122.7732	123.4033	123.3159	122.4486
CLS_OS	258.0909	263.7364	261.7808	261.5405	259.8134
RALS_PFS	272.4691	268.5883	266.3684	266.5356	265.3710
CLS_PFS	502.6661	507.5606	504.8710	504.3407	502.3186

表2.生存曲线的分布参数

KMcurves	Optimalfittingdistribution	Parameter
RALS_OS	Exponential	rate=0.000886894
CLS_OS	Exponential	rate=0.00103057
RALS_PFS	Log-normal	meanlog=5.041206;sdlog=0.991065
CLS_PFS	Log-normal	meanlog=5.72101;sdlog=1.48265

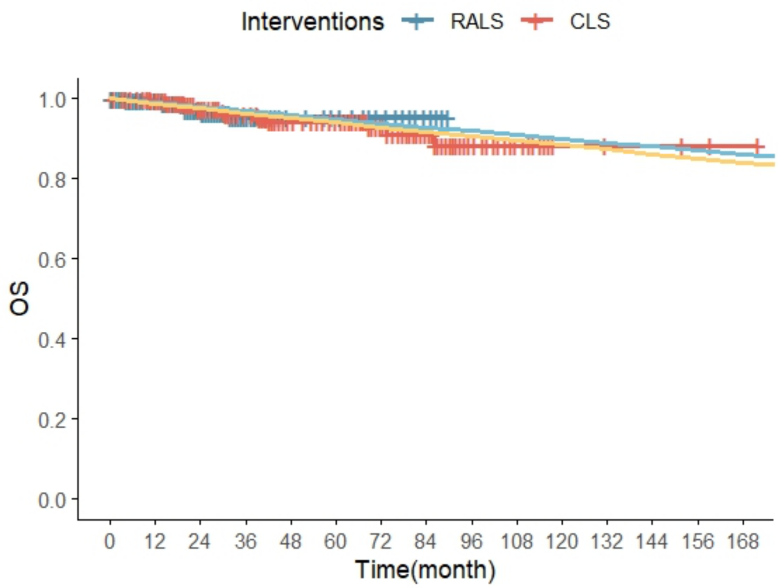

图2.两种手术OS曲线的最佳拟合外推结果

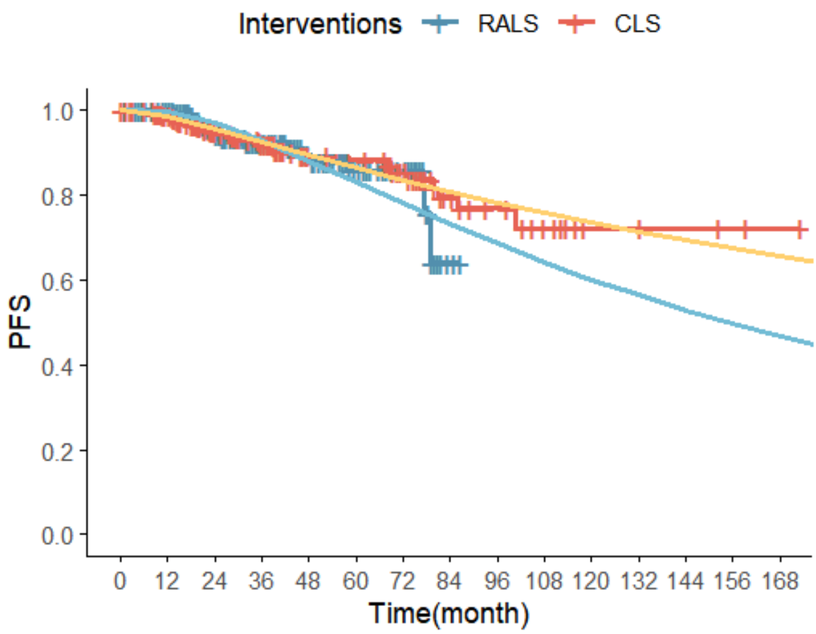

图3.两种手术PFS曲线的最佳拟合外推结果

缩写：RALS，机器人辅助腹腔镜手术；CLS，传统腹腔镜手术；PFS，无进展生存。

成本估计从社会角度进行，主要关注直接医疗成本和间接成本，由于数据可获得性限制，不包括交通费用等直接非医疗成本（Janda et al.,2017）。部分数据，如健康效用值，来源于已发表文献。直接医疗成本包括手术费用、机器人设备购置和维护成本、Endowrist专用耗材成本、手术室成本以及复发和转移阶段的化疗成本等。在模型背景下，假设每个周期内仅发生一次由化疗引起的≥3级不良事件。关于间接成本，本研究仅考虑陪同患者就医的家庭成员的生产力损失，假设每位患者至少有一名家庭成员陪同。由于中国大多数女性在55岁左右退休，因此在分析中未考虑患者自身的生产力损失。生产力损失根据住院时间和2023年中国人均每日可支配收入进行估计。为考虑货币的时间价值，根据文献数据的调查年份和中国消费者物价指数（CPI）将成本调整为2023年的值。

表3. 决策分析马尔可夫模型的成本和效用参数

Parameter	BaseValue	SD	Range	Distribution
Directcosts				
Operationcosts(¥)				
Standardstagingsurgery[a]	2,565.00	261.73	2,052.00-3,078.00	Gamma
Additionalcharge(withlaparoscopy)[b]	200.00	20.41	160.00-240.00	Gamma
Roboticequipment(¥)				
Purchase_IS4000[c]	26,388,200.00	1,675,487.75	23,998,000.00-27,998,000.00	Gamma
Maintenance/year[c]	1,867,428.57	158,859.74	1,530,000.00-1,980,000.00	Gamma
Consumables_Endowrist	19,929.78	2,033.65	15,943.82-23,915.74	Gamma
Operatingroomcosts(¥/hour)				
Constructioncosts	1,211.74	154.56	908.81-1,514.68	Gamma
Inventorycosts[d]	4,164.72	531.21	3,123.54-5,205.90	Gamma
Personnelcosts[e]	3,105.73	396.14	2,329.30-3,882.16	Gamma
Overheadcosts[f]	1,639.41	209.11	1,229.56-2,049.26	Gamma
Operativetime(hour)				
RALS	4.54	2.72	3.63-5.45	Normal
LPS	3.84	2.27	3.07-4.61	Normal
Depreciablelifeofroboticequipment(year)	8.00	1.28	5.00-10.00	Normal
Annualoperationvolume_RALS	250.00	229.59	100.00-1000.00	Normal
Inpatientdiagnosticfee(¥/day)	25.00	2.55	20.00-30.00	Gamma
Wardfee(¥/day)	47.00	4.80	37.60-56.40	Gamma
Nursingfee(Grade2,¥/day)	12.00	1.22	9.60-14.40	Gamma
Drugcosts_chemotherapy				
Carboplatin(10ml:100mg)	51.60	5.27	41.28-61.92	Gamma
Paclitaxel(5ml:30mg)	67.23	6.86	53.78-80.68	Gamma
Bestsupportivecarepertime	1,253.44	127.92	1,002.72-1,504.15	Gamma
Routinefollow-uppertime	507.07	51.73	405.68-608.46	Gamma
Laboratorytestsandradiologicalexaminations	2,457.90	250.81	1,966.31-2,949.50	Gamma
≥Grade3AEscosts				
Anemia	2,315.45	236.29	1,852.33-2,778.57	Gamma
Neutropenia	3,124.55	318.83	2,499.65-3,749.45	Gamma
Neutrophilcountdecreased	3,124.55	318.83	2,499.65-3,749.45	Gamma
White-cellcountdecreased	1,450.30	147.99	1,160.24-1,740.35	Gamma
Indirectcosts				
Lengthofstay/Sickleave(day)				
RALS	11.59	3.58	9.27-13.91	Normal
CLS	11.89	5.37	9.51-14.27	Normal
Percapitadisposableincome(¥/day)	107.45	10.96	85.96-128.94	Gamma
Others				
Bodysurfacearea(m^2)	1.69	0.17	1.35-2.03	Normal
Weight(Kg)	59.00	6.02	47.20-70.80	Normal
Discountrate	0.05	0.02	0.00-0.08	Beta

Creatinineclearancerate(ml/min)	70.00	7.14	56.00-84.00	Gamma
Utilityvalue				
PFS				
RALS	0.87	0.09	0.70-1.00	Beta
CLS	0.75	0.02	0.60-0.90	Beta
PD	0.63	0.06	0.60-0.90	Beta

三、结果

基础案例分析结果见表4。CLS组和RALS组的累积成本分别为732,822.83元和1,163,581.06元。与CLS组相比，RALS组患者获得的QALYs多1.03个，但需额外花费430,758.23元，由此得出的ICER为417,201.84元/QALY，超过预先设定的WTP阈值（275,238元/QALY）。结果表明，在早期EC的治疗中，与CLS相比，RALS在成本-效果方面无优势。

表4. 基础案例分析结果

Outcomeindicators	CLS	RALS
Cumulativecosts(¥)	732,822.83	1,163,581.06
Incrementalcosts(¥)	-	430,758.23
Cumulativeeffectiveness(QALYs)	9.42	10.45
Incrementaleffectiveness(QALYs)	-	1.03
ICER(¥/QALY)	-	417,201.84

龙卷风图（图 4）确定了对模型结果影响最大的六个变量：RALS 年手术量、RALS 手术时间、CLS 手术时间、PD 状态的效用值、机器人设备折旧年限和 Endowrist 耗材成本。模型对其他参数的变化敏感性较低，包括机器人设备购置和维护成本、贴现率以及两组的住院时间，表明这些因素对总体结果影响较小。

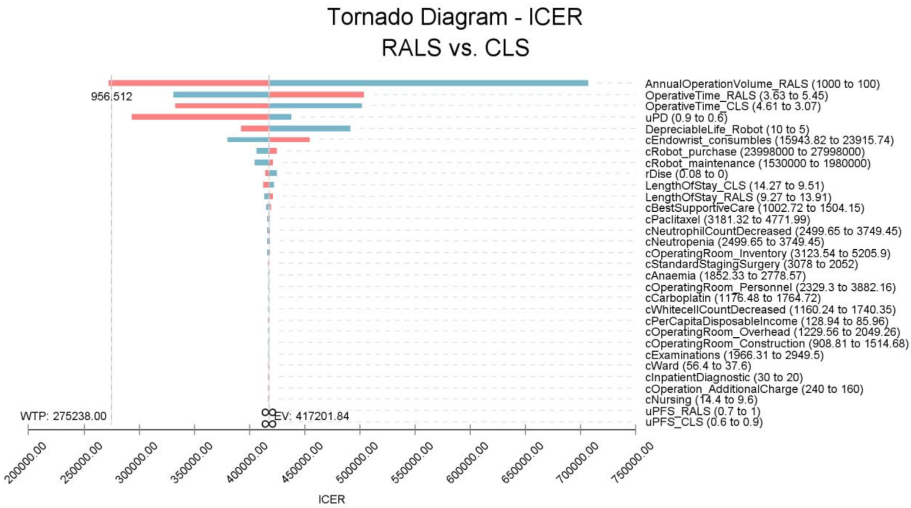

图4.单因素敏感性分析龙卷风图

进一步研究模型发现，随着 RALS 组年手术量的增加，RALS 与 CLS 组之间的 ICER 值降低，逐渐接近预设的 WTP 阈值。当每台机器人设备的年手术量达到 947 例时，RALS 将成为更具成本效益的手术策略。这也表明，随着年手术量的增加，RALS 组具有成本效益的可能性增大。

表5.单因素敏感性分析（年手术量）

Outcomeindicators	CLS	RALS		
		100	550	1000
Cumulativecosts(¥)	732,822.83	1,462,322.35	1,054,947.86	1,014,210.41
Incrementalcosts(¥)	-	729,499.52	322,125.03	281,387.58
Cumulativeeffectiveness(QALYs)	9.42	10.45	10.45	10.45
Incrementaleffectiveness(QALYs)	-	1.03	1.03	1.03
ICER(¥/QALY)	-	706,541.44	311,987.44	272,532.04

缩写：RALS，机器人辅助腹腔镜手术；CLS，传统腹腔镜手术；QALYs，质量调整生命年；ICER，增量成本效益比。

表6.阈值分析

Variable	Baseline	ICER(¥/QALY)	WTP(¥/QALY)	Threshold
Annualoperationvolume_RALS	250	155769.06	275,238.00	946.87

缩写：RALS，机器人辅助腹腔镜手术；QALY，质量调整生命年；ICER，增量成本效益比；WTP，支付意愿。

ICER 散点图（图 5）展示了 1000 次蒙特卡洛模拟的结果。大部分模拟的 ICER 值位于 95%置信区间内，表明分析结果稳定。值得注意的是，43.1%的模拟 ICER 值低于 WTP 阈值（275,238 元/QALY），这意味着 RALS 有 43.1%的概率更具成本效益。

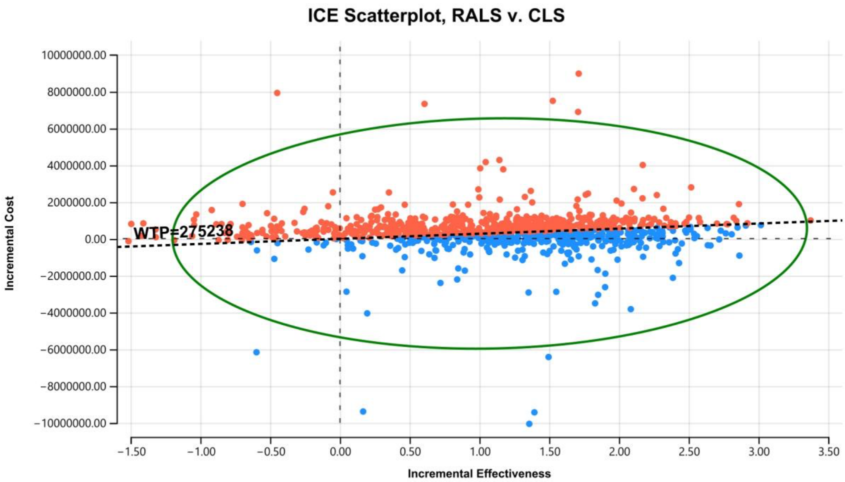

图5：ICER散点图

此外，图 6 展示了成本-效果可接受性曲线。随着 WTP 阈值的增加，RALS 具有成本效益的概率也随之上升。特别是当 WTP 为 357,809.40 元/QALY 时，RALS 和 CLS 具有成本效益的概率相等。超过该阈值后，RALS 具有成本效益的概率越来越高，表明在较高 WTP 情景下，RALS 相比 CLS 具有潜在的经济优势。

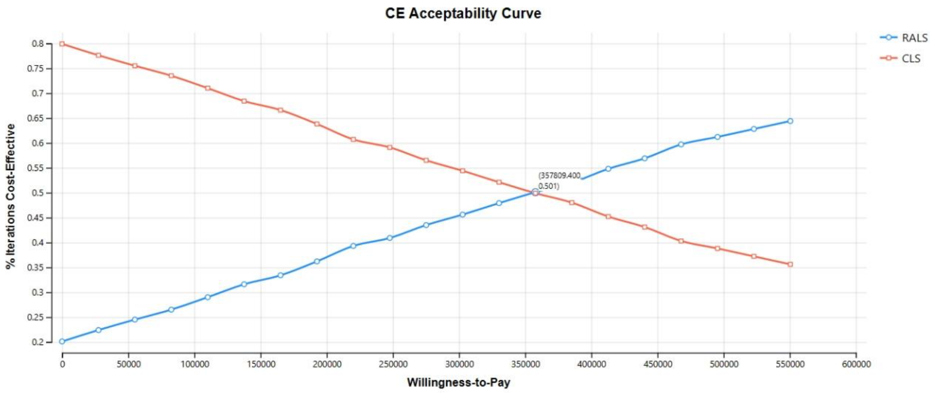

图6：成本-效果可接受性曲线

缩写：RALS，机器人辅助腹腔镜手术；CLS，传统腹腔镜手术。

四、讨论

本研究的基础案例和敏感性分析结果一致表明，与传统腹腔镜手术（CLS）相比，机器人辅助腹腔镜手术（RALS）在早期子宫内膜癌（EC）治疗中并不具备成本效益。分析指出，尽管 RALS 能够产生更好的健康结果，但它需要更多的资源利用并产生比 CLS 更高的成本。然而，如果每台机器人执行的年度手术量或支付意愿（WTP）阈值增加，RALS 的成本效益潜力将会提高。

相关研究显示，RALS 的高成本主要归因于机器人购买和维护的费用以及一次性器械的成本。这一点也在我们单变量敏感性分析的龙卷风图中有所体现。尤其是，LeitaoMMJr.等人进行的研究发现，除去初始设备购置成本，RALS 在子宫癌管理上与 CLS 相当。

McCarthy A 等人进行的另一项研究评估了 RALS 与 CLS 在妇科恶性肿瘤治疗中的成本效益，发现 RALS 在调整发病率差异之前并不具备成本效益。在这项研究中，他们进一步发现随着机器人设备使用频率的增加，RALS 的潜在成本效益也随之提高。我们的研究结果与这一观察一致。随着年度手术量的增加，由于设备高昂的购置和维护费用，每次手术的摊销成本降低，从而增强了机器人手术的潜在经济可行性。敏感性分析表明，

在当前支付意愿阈值为人均 GDP 三倍的情况下，年度手术量是机器人辅助手术项目潜在经济可行性的唯一决定因素。这强调了医院在考虑新机器人购置时需考虑手术量，并最大化已投资机器人的使用。在未来更广泛的应用中，机器人辅助腹腔镜手术有可能成为一种更具经济效益的治疗选择。

虽然上述研究表明 RALS 相比 CLS 可能提供成本效益，但需承认这一结论受诸如机器人设备使用频率和患者病例复杂性等因素影响。因此，进一步研究是验证这一结论的必要。此外，还需更多研究来探索 RALS 在中国更广泛采用的促进因素，并识别优化其成本效益的策略。

尽管腹腔镜手术机器人具有广泛适用性，其临床采用仍然有限，主要原因是设备购置和维护的高昂成本。此外，机器人手术在中国众多地区未被纳入医疗保险政策，加重了患者及其家庭的经济负担。从长远来看，通过医疗保险报销促进对批准外科机器人普遍可及性成为一种潜在策略，尽管这对国家医疗基金以及所有程序和地区的手术费用全面覆盖提出了挑战。此外，现有机器人平台中孔放置技术和腕旋转工具的使用改变了传统腹腔镜手术的操作模式，固有地提高了复杂性和对外科医生的挑战。因此，外科医生必须经过严格的技能培训并结合广泛的临床实践，以达到熟练操作腹腔镜手术机器人的水平。

近年来，在国家政策、人口老龄化和技术进步的推动下，中国腹腔镜手术机器人产业经历了快速增长，涌现出如天智航、精锋医疗和北京术锐等知名企业，其产品相继获得市场批准或进入临床试验。去年，首台中国制造的达芬奇手术系统（IntuitiveFosun，IS4000CN）正式推出，标志着全球知名的达芬奇手术机器人在中国的正式本地化。随后，在 2023 年 12 月 1 日，首台中国制造的达芬奇 IS4000CN 成功竞标，成交价为¥19,780,000。机器人设备的购置成本大幅降低。如果能在降低维护和专用耗材成本方面取得显著进展，RALS 可能会成为一种更具经济吸引力的治疗选择。尽管 IS4000CN 的出现，仍缺乏关于其临床表现的实证数据。因此，未来的研究工作必须系统地调查和阐明中国制造的达芬奇与 Intuitive Surgical 生产的产品之间可能存在的临床结果差异。这些研究不仅将有助于外科机器人技术的进步，还将为临床决策提供信息并提升患者护理。

从中国社会的角度来看，我们的研究通过决策分析马尔可夫模型评估了 RALS 和 CLS 在早期 EC 治疗中的成本效益。然而，本研究存在一定的局限性。首先，数据来源有限。由于缺乏特定于中国人口的生存数据和术后生活质量报告，参考了其他国家的相关研究来计算健康状态之间的转移概率并确定每个状态的效用值，可能会引入研究结果的偏差。这强调了中国研究人员未来需开展更多针对本地人口的早期 EC 手术临床研究，以完善生存分析并丰富基础数据。其次，为简化模型结构，本研究假设在术后疾病进展阶段将实施化疗结合最佳支持治疗，这可能与患者和临床医生在实际医疗实践中的选择不符。

五、结论

从中国社会的角度来看，在每获得一个质量调整生命年（QALY）支付意愿（WTP）阈值为¥275,238 的情况下，RALS 相较于 CLS 不太可能成为晚期子宫内膜癌的成本效益治疗选择。当年度手术量达到 947 例或支付意愿阈值提高时，RALS 可能具备成本效益。因此，政策制定者和医疗服务提供者在评估 RALS 在临床实践中的实施时，应考虑这些因素，尤其是在年度手术量较高或社会对健康投资意愿较大的地区。

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