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PEKING UNIVERSITY
全球健康发展研究院
PKU INSTITUTE FOR
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智慧手术季刊

SMART Surgical Quarterly

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Parallel Studies

Global News

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（An Internal Journal）

智慧手术季刊

SMART Surgical Quarterly

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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SMART Surgical Quarterly

第4期 2024年12月

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平行研究

动态摘编

（内部交流季刊）

Robot Adoption in Chinese Hospitals: Analysis Plan

By KWAN TING LEUNG YUHANG PAN*

We empirically examine the impact of the first-time using of medical robots on department level performance in China. Employing a robust analytical framework combining Two-Way Fixed-Effect (TWFE) and Event Study methodologies, we analyze daily department data spanning from Jan 2013 to Dec 2022. Our focus is on quantifying the shifts in ln total revenue following the first-time using of this advanced surgical technology.

Due to its unprecedent economic development and increasingly growing demands, China has become one of the fastest-growing markets for the surgical robotics developer. This short article briefly reviews the technology adoption of da Vinci surgical system (da Vinci RAS) in Chinese hospitals, especially at the hospital department level. As of 2022, da Vinci RAS was recognized as the largest provider of robotic-assisted surgical (RAS) technology training to be accredited, and nearly 7000 da Vinci RAS have been installed in more than 70 countries, with more than 10 million minimally invasive robotic surgical procedures performed (Xue et.al, 2021).

The da Vinci surgical system was first introduced in China in 2006, where it was adopted at Chinese PLA General Hospital. Over the period from 2006 to 2023, a total of 284 Chinese hospitals have implemented the da Vinci RAS system. This technology has then been utilized by approximately 2,300 surgeons among a diverse range of surgical procedures. These surgeons have performed over 180 kinds of procedures, with the highest volume observed in Urology at around 150 thousand procedures.

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* Leung: Institute for Global Health and Development, Peking University (e-mail: kwanting@stu.pku.edu.cn); Pan (Corresponding Author): Institute for Global Health and Development, Peking University (e-mail: yhpan@pku.edu.cn). We thank Da Vinci for providing the market data. All errors are our own.

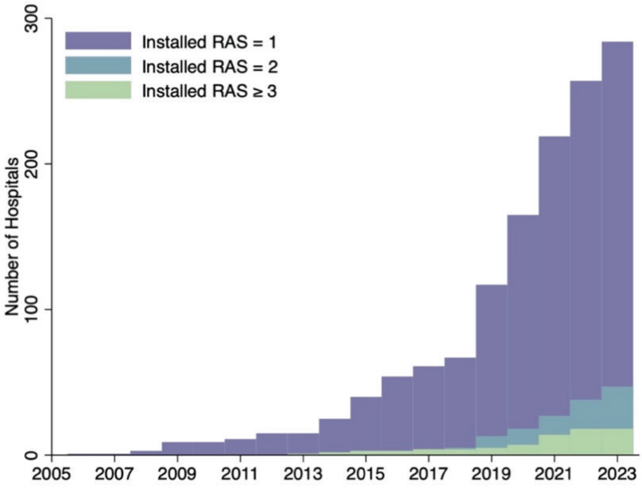


Figure 1. Number of Chinese Hospitals with da Vinci RAS

The adoption of da Vinci systems in Chinese hospitals encompasses four distinct models: DaVinci SP, DaVinci S, DaVinci Si, and DaVinci Xi. Our focus lies in examining the inaugural procedures performed using the da Vinci system within each category and across various hospital-department pairings. Figure 1 depicts the prevalence of da Vinci RAS systems across Chinese hospitals. Two notable periods of growth are observed. The first eye-catching growth occurred in 2014, where the number of hospitals with the da Vinci system nearly doubled. The second substantial growth took place around 2019, resulting in a rise from 69 hospitals to 119 hospitals with da Vinci systems.

Figure 2 illustrates the time lag between the installation of the da Vinci RAS system and its initial application across various surgical departments. The data suggest that General Surgery and Urology departments show a short interval from system installation to operation, possibly due to the high demands and immediate applicability of the da Vinci RAS for procedures common to these fields. The da Vinci RAS system is leveraged for an extensive array of procedures. For Urology, it can perform oncological management of prostate, kidney, and bladder cancers. In the sphere of General Surgery, the RAS system is for intricate removal of gastrointestinal malignancies, including gastric and colorectal cancers. Thoracic Surgery harnesses the advanced capabilities of the RAS for conditions like lung and esophageal cancers. For Gynecology, the da Vinci can be used to hysterectomies and managing gynecologic cancers. Building upon the classification initiated in Figure 2, the analysis extends to the level of hospital departments, incorporating additional specialties such as Pediatrics, Gastroenterology, Hepatobiliary Pancreatic, and Thyroid. As presented in Figure 3, only the Thyroid department exhibited a notable delay between the installation of RAS systems and their operational use, suggesting a latent phase of adoption for certain specialties.

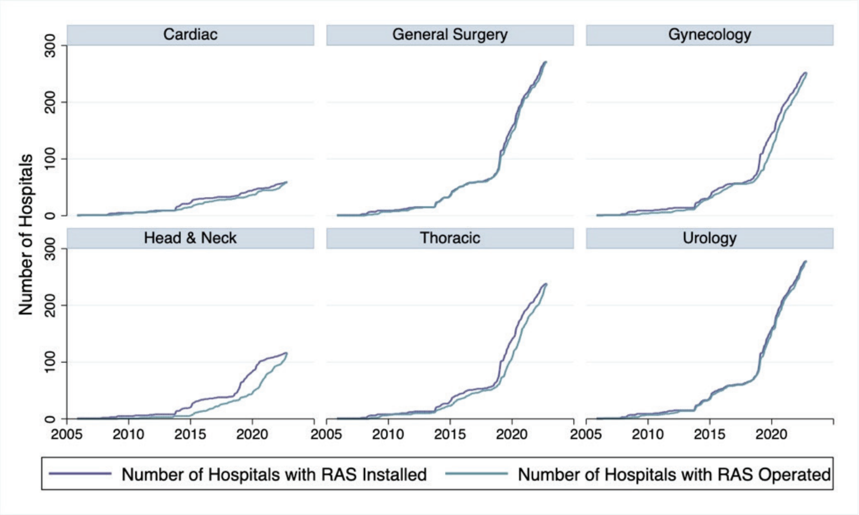


Figure 2. Installation and Operation of RAS by Category

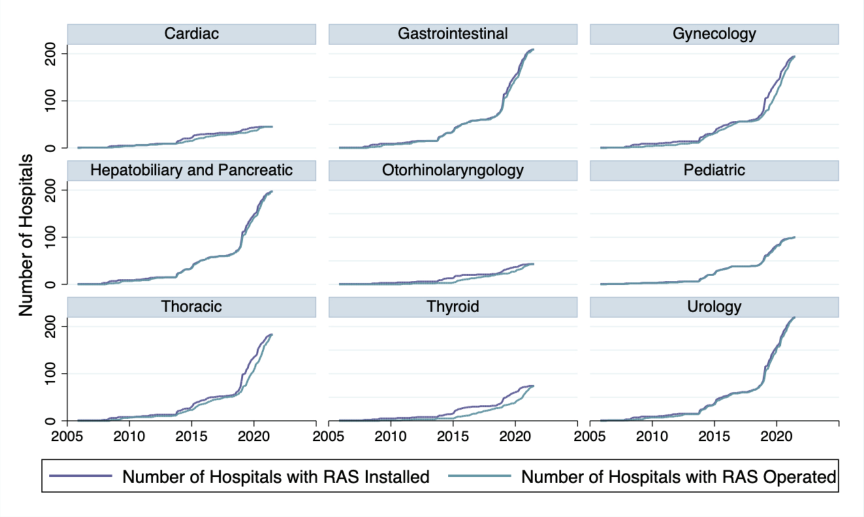


Figure 3. Installation and Operation of RAS by Hospital Departments

I. Data

The patient-level data, with each observation representing information for a single patient's entire stay, is aggregated at the department level daily. The data includes patient characteristics, spending, length of stay, and dates of admission and discharge.

Due to the lack of information on daily patient payments, we make three assumptions regarding how hospitals collect these payments. First, the hospital collects an equal amount daily; second, the hospital collects a lump sum on the date of admission; third, the hospital collects a lump sum on the date of discharge.

Assuming that patients spend the same amount of money each day during admission, daily revenue is calculated by using their total spending divided by the length of stay. Assuming that the hospital charges once at admission, total revenue on the admission date is calculated by adding up the total spending of each patient on the date of admission. Assuming that the hospital charges once at discharge, total revenue on the discharge date is calculated by adding up the total spending of each patient on the date of discharge.

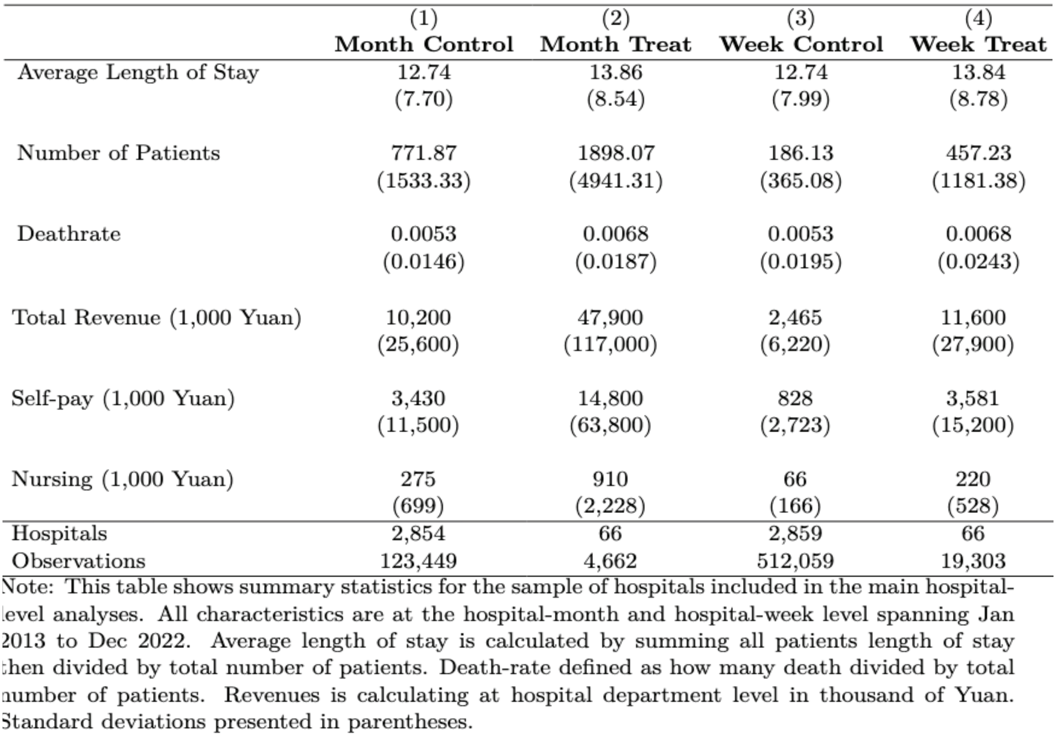
The two-digit number Age Gender contains information about the patient's gender and age. Gender includes 1 for male, 2 for female, and 3 for unknown. Six age groups are assigned: 0-15, 16-30, 31-45, 46-60, 61-75, and above 76. Three types of patient characteristics are calculated: first, cumulative for all patients currently in the hospital; second, for patients who have just been admitted; third, for discharged patients.

II. Summary Statistic

The summary statistics presented in Table 1 provides an overview of hospital-level metrics across the control and the treatment groups, segmented by month and week levels. Key indicators include average length of stay, number of patients, department level death rate, total revenue, self-pay revenue, and nursing revenue, all measured over the period from January 2013 to December 2022.

The mean number of patients admitted is substantially higher in the treated group, suggesting that hospitals with the da Vinci system may handle more complex or advanced cases or these hospitals with da Vinci are generally San Jia hospital with larger compacity for more patients. Although treatment group on average have 2.5 times patients compare to control group, they make almost 4.7 times more on department total income, total self-pay, and nursing revenue.

TABEL 1: SUMMARY STATISTICS FOR HOSPITALS IN SAMPLE(IN THOUSANDS)



	(1) **Month Control**	(2) **Month Treat**	(3) **Week Control**	(4) **Week Treat**
Average Length of Stay	12.74 (7.70)	13.86 (8.54)	12.74 (7.99)	13.84 (8.78)
Number of Patients	771.87 (1533.33)	1898.07 (4941.31)	186.13 (365.08)	457.23 (1181.38)
Deathrate	0.0053 (0.0146)	0.0068 (0.0187)	0.0053 (0.0195)	0.0068 (0.0243)
Total Revenue (1,000 Yuan)	10,200 (25,600)	47,900 (117,000)	2,465 (6,220)	11,600 (27,900)
Self-pay (1,000 Yuan)	3,430 (11,500)	14,800 (63,800)	828 (2,723)	3,581 (15,200)
Nursing (1,000 Yuan)	275 (699)	910 (2,228)	66 (166)	220 (528)
Hospitals	2,854	66	2,859	66
Observations	123,449	4,662	512,059	19,303

Note: This table shows summary statistics for the sample of hospitals included in the main hospital-level analyses. All characteristics are at the hospital-month and hospital-week level spanning Jan 2013 to Dec 2022. Average length of stay is calculated by summing all patients length of stay then divided by total number of patients. Death-rate defined as how many death divided by total number of patients. Revenues is calculating at hospital department level in thousand of Yuan. Standard deviations presented in parentheses.

III. Empirical Model

In this section, we present the empirical analysis to assess the impact of the first-time usage of the da Vinci Surgical System on various departmental outcomes. Our analysis employs a Difference-in-Differences (DID) approach, leveraging a panel dataset of hospitals and departments to estimate the causal effects of this advanced surgical technology. Below, we outline the empirical model, discuss our identification strategy, and summarize the main findings.

We estimate the impact of the da Vinci Surgical System installation using a generalized DID approach, where our outcome variables $Y_{i,j,t}$ are regressed on a set of event-time dummies representing the periods before and after the installation. The model is specified as follows: (He and Wang, 2017)

$$Y_{i,j,t} = \alpha + FirstProc_{i,j,t} + \rho_{i,j} + \vartheta_t + \epsilon_{i,j,t}$$

where $Y_{i,j,t}$ is the outcome for hospital i department j in year t, $FirstProc_{ijt}$ is a dummy indicator that equals 1 if hospital i department j in year t has started to use the da Vinci robotic system, and 0 otherwise. v_t is the fixed effect on time, and ρ_{ij} is the fixed effect on hospital departments. Standard errors are clustered at hospital and department level.

The DID identification strategy relies on the variation in the timing of the da Vinci system first-time using across hospitals and departments. By comparing the outcomes of departments before and after the installation or first-use, and against departments that have not yet adopted the system, the DID approach aims to isolate the causal effect of the da Vinci system from other confounding factors.

IV. Test for parallel trend with Event Study

Since both hospital department fixed effects and time fixed effects are included in the regressions, our empirical strategy essentially follows a generalized difference-in-differences model. To ensure that the trends in the outcomes between the treated and control groups are parallel before the usage of the da Vinci Surgical System, we employ an event study approach. Following Jacobson et al. (1993) and He and Wang (2017), we estimate the following equation:

$$Y_{ijt} = \alpha_{ij} + \delta_t + \beta_k \times \sum_{k=24}^{k\leq -12,\, k\neq 1} D_{ijt}^{k} + \epsilon_{ijt}$$

Our outcome variables Y_{ijt} is a mix of payment variables for hospital i in department j at time t. Y_{ijt} includes monthly total revenue, revenue from self-pay to nursing revenues.

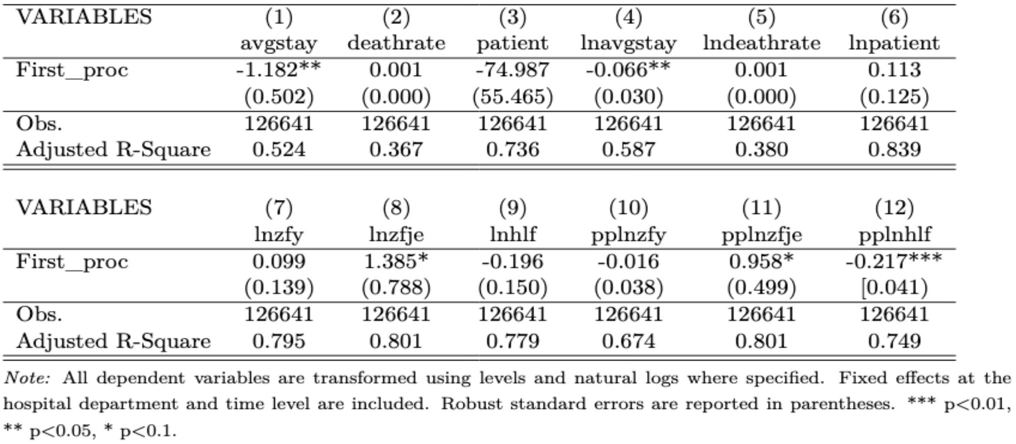
The dummy variable D_{ijt} jointly represent the da Vinci first-time using event, define s_i as the year when hospital i department j first install the da Vinci robotic system. We define $D_{ijt}^{-12}=1$ if $t-s_i\leq-12$ and 0 otherwise. In the baseline model we control fixed effects α_{ij} at the hospital level i department j and time fixed effect δ_t. Standard errors are clustered at hospital department level.

V. Baseline results

Table 2 reports the results of the Monthly DID regression analysis. The results indicate that the first-time usage of the da Vinci system is associated with a significant reduction in the average length of stay, with a coefficient for first_proc of -1.181, significant at the 5% level. This suggests that patients spend approximately one day less in the hospital after the initial use of the da Vinci system, reflecting increased efficiency and effectiveness of robotic-assisted surgical procedures. On the log form of average length of stay we found a 5% level significant reduction of -0.066%. Continue on patient outcome, we found that the impact on mortality rate is not statistically significant, as the coefficient is close to zero. This finding aligns with the surgeon's qualitative insights that the da Vinci system does not significantly alter patient risk in terms of mortality.

Regarding departmental revenue, we found significant increase of 1.385 on self-pay revenue, this is likely due to China insurance policy does not cover high-end technology surgery. Beside the da Vinci, Patient can choose to conduct laparoscopic surgery for about ¥ 5,000 which are covered by insurance. However, conducting the da Vinci system means that the patients have to pay 100% of ¥30,000. We do not observe significant effects from the first-time use of the da Vinci system on other department outcome, total revenue (0.099), nursing revenue (-0.196). However, there is a significant decrease in per person nursing revenue (-0.1955, significant at the 1% level), suggesting that patients incur lower nursing costs due to shorter hospital stays.

Table 2: Month DID regression Results



VARIABLES	(1) avgstay	(2) deathrate	(3) patient	(4) lnavgstay	(5) lndeathrate	(6) lnpatient
First_proc	-1.182**	0.001	-74.987	-0.066**	0.001	0.113
	(0.502)	(0.000)	(55.465)	(0.030)	(0.000)	(0.125)
Obs.	126641	126641	126641	126641	126641	126641
Adjusted R-Square	0.524	0.367	0.736	0.587	0.380	0.839

VARIABLES	(7) lnzfy	(8) lnzfje	(9) lnhlf	(10) pplnzfy	(11) pplnzfje	(12) pplnhlf
First_proc	0.099	1.385*	-0.196	-0.016	0.958*	-0.217***
	(0.139)	(0.788)	(0.150)	(0.038)	(0.499)	[0.041)
Obs.	126641	126641	126641	126641	126641	126641
Adjusted R-Square	0.795	0.801	0.779	0.674	0.801	0.749

Note: All dependent variables are transformed using levels and natural logs where specified. Fixed effects at the hospital department and time level are included. Robust standard errors are reported in parentheses. *** $p<0.01$, ** $p<0.05$, * $p<0.1$.

VI. Event Study Results

Figure 4 visualize the dynamic effects by displaying the point estimates of self-pay revenue on department level, along with their 95\% confidence intervals. Each point represents an estimated coefficient of the treatment dummy variable for a different number of weeks or months before or after the event. Notably, out-of-pocket revenue exhibits a strong increasing trend starting from month 7, indicating a substantial positive impact of the da Vinci system on patient expenses. Nursing revenue on the second graph display a negative trend starting from month 6, with significance at the 5% level by month 12 and beyond.

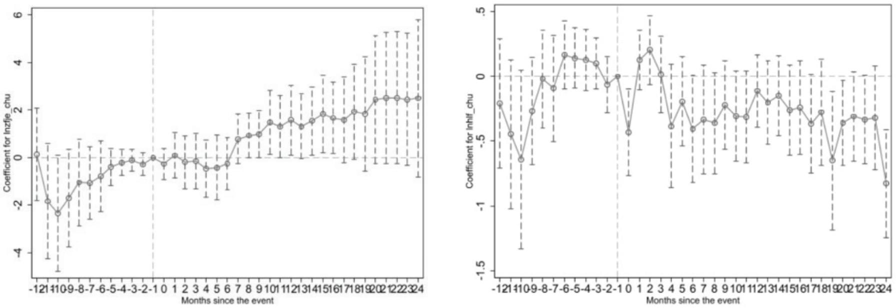


Figure 4. Event Study for Self-Pay Revenue and Nursing Revenue

VII. Robustness Checks

For robustness check we conducted studies with Event DD and Stagger DID and did not find conflict coefficients.

VIII. Heterogeneity

We conducted additional DID regression and Event Study using each department data only. We choose departments that have a high amount of da Vinci machines, which include Cardiac, General Surgery, Gynecology, Thoracic, to Urology. We also filter the data to focus on department with more elderly patients and the youngest patients. Lastly, we split gender in order to see the effect of using da Vinci on different gender.

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Health Economics Study of Robots and Laparoscopy for Hepatocellular Carcinoma Resection

By Xiao Liang Haijing Guan Junhao Zheng AND Chenyue Yang*

Compared to laparoscopic liver resection, robotic liver resection can reduce postoperative complication rates and hospital stay, and improve patients' postoperative quality of life. However, the costs of robotic liver resection are relatively high, and there is currently a lack of evidence from China on whether robotic liver resection for hepatocellular carcinoma is cost-effective. To explore the clinical value and medical costs of robotic liver resection compared to laparoscopic liver resection for hepatocellular carcinoma. We retrospectively collected data from patients with hepatocellular carcinoma who underwent minimally invasive liver resection by a single medical team at Sir Run Run Shaw Hospital of College of Medicine of Zhejiang University from January 2016 to July 2023. Patients were divided into the study group (robotic liver resection group) and the control group (laparoscopic liver resection group). After propensity score matching, we compared perioperative indicators and medical costs before and after matching and conducted subgroup analyses with surgical difficulty as a covariate to analyze the differences in perioperative outcomes and medical costs between the two surgical methods under different surgical difficulties. A total of 277 patients were included in this study (175 in the laparoscopic liver resection group and 102 in the robotic liver resection group). After controlling for baseline characters using propensity score matching, 162 patients (81 in each group) were included for further analysis. The results showed that the robotic liver resection

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* Liang: Sir Run Run Shaw Hospital, Zhejiang University (email: 3190104362@zju.edu.cn); Guan: Beijing Tiantan Hospital, Capital Medical University; Zheng: Sir Run Run Shaw Hospital, Zhejiang University; Yang: Sir Run Run Shaw Hospital, Zhejiang University

group had less intraoperative bleeding, fewer postoperative complications, a lower conversion to open surgery rate, and better surgical safety compared to the laparoscopic liver resection group. The robotic liver resection group had higher medical costs (¥82,885.3 vs. ¥58,643.8, $p<0.001$); however, the non-surgical costs of laparoscopic liver resection group is significantly higher costs higher than robotic liver resection group. The subgroup analysis indicates that there was no significant difference in costs between the two surgical methods in high-difficulty liver resections. For patients with hepatocellular carcinoma, robotic liver resection has better surgical safety and higher medical costs compared to laparoscopic liver resection. Simultaneously, robotic liver resection appears to be more cost-effective for patients with high surgical difficulty.

I. Background

Robotic liver resection (RLR), as a new technology, may offer better surgical safety compared to laparoscopic liver resection (LLR), though it tends to be more costly. Therefore, whether using robotic resection for the treatment of hepatocellular carcinoma (HCC) is economically effective remains to be evidenced due to the current lack of related proof.

Currently, there are few reports on the health economics of robotic liver resection both domestically and internationally. A meta-analysis in 2022, which included four relevant studies, showed that the cost of RLR (USD 20,205.92) is significantly higher than that of LLR (USD 15,789.75). Cost is a major factor restricting the implementation of RLR (Ciria et al., 2022). However, with the development of modern medicine, surgery aims not only to cure but also to improve the quality of life. In 2020, Mejia et al. reported on 214 liver resection patients and indicated that, despite the higher costs, RLR resulted in shorter hospital stays compared to LLR, making it a better choice for patients requiring minor liver resections (Mejia et al., 2020). Nonetheless, in 2016, Chinese researchers, based on data from 39 patients undergoing robotic and laparoscopic left lateral liver lobe resection, pointed out that RLR is more expensive than LLR for left lateral liver lobe resection, but there is no statistically significant difference in efficacy and safety (Yin et al., 2016). Therefore, whether RLR can improve quality of life and be cost-effective remains a debate.

The 2023 International Guidelines for Robotic Liver Resection experts pointed out that, compared to LLR, RLR has unique therapeutic value in liver-related diseases, and its cost-effectiveness merits further research (Liu et al., 2023). In disciplines such as urology and colorectal surgery, studies have suggested that robotic surgery is cost-effective or highlighted the cost reductions needed to improve the adoption rate of robots (Simianu et al., 2020; Song et al., 2022).

II. Methods

Conduct real-world research, retrospectively collecting data on inpatients diagnosed with HCC at Sir Run Run Shaw Hospital affiliated with Zhejiang University from January 2016 to July 2023. Patients were divided into RLR and LLR groups based on the type of surgery they underwent. On the basis of descriptive analysis, confounding factors were controlled through propensity score matching (PSM) to explore the net benefits of different treatment methods on treatment outcomes and medical costs, and to conduct an economic evaluation. Subgroup analyses were carried out to explore the robustness of the research results.

Continuous variables with a normal distribution are described as mean ± standard deviation, while those with a skewed distribution are described as median (interquartile range), and categorical variables are described as frequency and percentage. Age, BMI, AFP, INR, ALB, AST, TBIL, Child-Pugh classification, vascular invasion, difficulty of operation, and ASA classification were included as covariates in the model for fitting, and propensity scores were calculated for nearest neighbor matching. PSM analysis was conducted using SPSS version 25.0. Patients were divided into four subgroups based on IWATE surgical difficulty grading as “Low”, “Intermediate”, “Advanced”, and “Expert” for subgroup analysis. (Figure 1)

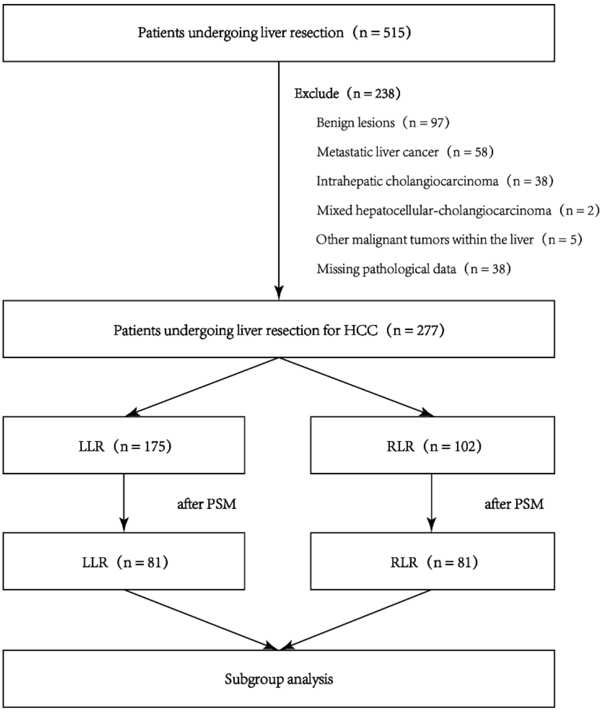

FIGURE 1. INCLUSION AND EXCLUSION CRITERIA AND FLOWCHART

III. Results

After applying the inclusion and exclusion criteria, a total of 277 patients were included in this study. They were divided into the LLR group (175 patients) and the RLR group (102 patients) based on the surgical method. After PSM, 81 patients in each group were further analyzed and compared.

A. baseline characteristics of the patient

Before PSM, the LLR group had significant differences compared to the RLR group in BMI, AFP, PLT, INR, ALB, AST, liver cirrhosis, Child-Pugh classification, portal hypertension, and IWATE surgical difficulty classification (all $p < 0.05$). There were no significant differences in the remaining indicators. After balancing the baseline characteristics through PSM, 162 patients (81 in the LLR group and 81 in the RLR group) were included for further analysis, and there were no significant differences in baseline characteristics between the LLR and RLR groups (Table 1).

TABLE1 — BASELINE CHARACTERISTICS OF THE LLLR AND RLR GROUPS BEFORE AND AFTER PSM

Baseline characteristics	before PSM (n=277)			after PSM (n=162)		
	LLR (n = 175)	RLR (n = 102)	p value	LLR (n=81)	RLR (n=81)	p value
Age (SD), year	58.7±12.2	60.6±11.5	0.056	62.9±11.6	61.4±11.2	0.390
BMI (SD), kg/^{m}2	23.2±2.8	24.1±3.6	**0.021**	23.6±3.0	24.0±3.3	0.406
Gender, n(%)			0.309			0.678
Female	23 (13.1)	18(17.6)		13(16.0)	15(18.5)	
Male	152 (86.9)	84(82.4)		68(84.0)	66(81.5)	
Tumor size (IQR), cm	2.6 (1.8-4.3)	3.0 (2.2-4.5)	0.163	2.5 (1.8-4.4)	3.2 (2.2-4.7)	0.082
AFP (IQR), ng/mL	17.2 (3.4-277.5)	6.6 (2.5-110.2)	**0.048**	10.2 (3.2-139.8)	6.6 (2.6-110.2)	0.403
PLT (IQR), ×10^{9}/L	126.0 (89.0-172.0)	143.5 (111.0-191.2)	**0.005**	124.0 (95.5-170.0)	138.0 (108.0-190.0)	0.050
PT (IQR), s	13.8 (13.1-14.6)	13.5 (13.0-14.2)	0.068	13.5 (12.9-14.1)	13.5 (13.1-14.2)	0.437
INR (IQR)	1.0 (1.0-1.2)	1.0 (1.0-1.1)	<0. 001	1.0 (1.0-1.1)	1.0 (1.0-1.0)	0.307
TBIL (IQR), μmol/L	14.9 (11.1-21.1)	14.8 (11.2-19.1)	0.728	14.2 (9.6-21.3)	15.3 (11.4-18.8)	0.589
ALB (SD), g/L	39.4±4.8	40.9±4..5	**0.013**	40.2±4.4	40.0±3.6	0.794
AST (IQR), U/L	27.0 (18.0-40.0)	30.0 (23.8-38.0)	**0.026**	25.0 (17.0-41.0)	29.0 (23.5-38.0)	0.100
ALT (IQR), U/L	29.0 (22.0-39.0)	27.0 (19.0-42.3)	0.364	29.0 (21.5-39.0)	27.0 (19.0-41.5)	0.559
Number of tumors, n(%)			0.819			0.658
Single	151(86.3)	87(85.3)		68(84.0)	70(86.4)	
Multiple	24(13.7)	15(14.7)		13(16.0)	11(13.6)	
Liver cirrhosis, n(%)	96(54.8)	41(40.2)	**0.016**	38(46.9)	32(39.5)	0.341
Child-Pugh classification, n(%)			0.049			1

A	159(90.9)	99(93.1)		78(96.3)	78(96.3)	
B or C	16(9.1)	3(2.9)		3(3.7)	3(3.7)	
Portal hypertension, n(%)	11(6.2)	0(0)	**0.028**	5(6.2)	0(0.0)	0.074
History of liver resection, n(%)	22(12.6)	14(13.7)	0.844	12(14.8)	12(14.8)	1
History of laparotomy, n(%)	56(32.0)	35(34.3)	0.693	27(33.3)	31(38.3)	0.512
History of neoadjuvant therapy, n(%)	25(14.2)	10(9.8)	0.279	6(7.4)	9(11.1)	0.416
IWATE tumor location (IQR)	5.0 (3.0-5.0)	5.0 (3.0-5.0)	0.949	5.0 (3.0-5.0)	5.0 (3.0-5.0)	0.576
IWATE tumor size (IQR)	0.0 (0.0-1.0)	1.0 (0.0-1.0)	0.179	0.0 (0.0-1.0)	1.0(0.0-1.0)	0.140
IWATE the extent of liver resection (IQR)	0.0 (0.0-4.0)	3.0 (0.0-4.0)	0.195	0.0 (0.0-4.0)	0.0 (0.0-4.0)	0.946
IWATE proximity to a major vessel (IQR)	0.0 (0.0-0.0)	0.0(0.0-0.0)	0.541	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.135
IWATE liver function (IQR)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	**0.049**	0.0 (0.0-0.0)	0.0 (0.0-0.0)	0.988
IWATE HALS/hybrid (IQR)	0.0 (0.0-0.0)	0.0 (0.0-0.0)	1	0.0 (0.0-0.0)	0.0 (0.0-0.0)	1
IWATE total score (IQR)	6.0 (5.0-9.0)	7.0 (5.0-9.0)	0.176	6.0 (4.0-9.0)	6.0 (4.5-9.0)	0.57
IWATE difficulty level, n(%)			0.003			0.916
Low	27(15.4)	19(18.6)		16(19.8)	16(19.8)	
Intermediate	82(46.9)	28(27.5)		29(35.8)	25(30.9)	
Advanced	31(17.7)	35(34.3)		21(25.9)	23(28.4)	
Expert	35(20.0)	20(19.6)		15(18.5)	17(21.0)	
ASA classification, n(%)			0.206			0.692
I	8(4.6)	1(1.0)		2(2.5)	1(1.2)	
II	155(88.6)	94(92.2)		72(88.9)	75(92.6)	
III	12(6.9)	7(6.9)		7(8.6)	5(6.2)	
IV~VI	0(0.0)	0(0.0)		0(0.0)	0(0.0)	
Type of medical insurance, n(%)			0.074			0.070
Basic medical insurance for urban workers	164(93.7)	101(99.0)		74(91.4)	80(98.8)	
The others	11(6.3)	1(1.0)		7(8.6)	1(1.2)	

Place of residence, n(%)			0.803			0.727
Local	47(26.9)	26(25.5)		24(29.6)	22(27.2)	
Nonlocal	128(73.1)	76(74.5)		57(70.4)	59(72.8)	

B. *clinical outcomes of the patients*

Before PSM, the LLR group had significantly higher intraoperative blood loss (100.0 ml vs. 50.0 ml, $p < 0.001$), intraoperative transfusion rate (33 [18.8%] vs. 10 [9.8%], $p = 0.045$), postoperative complication rate (35 [20.0%] vs. 7 [6.8%], $p = 0.003$), conversion to open surgery rate (20 [11.4%] vs. 0 [0.0%], $p = 0.001$), postoperative hospital stay (6.0 days vs. 5.0 days, $p = 0.001$), and total hospital stay (13.0 days vs. 9.5 days, $p = 0.001$) compared to the RLR group, with no significant differences in the remaining indicators (all $p \geq 0.05$).

After balancing baseline characteristics through PSM, a total of 162 patients (81 in the LLR group and 81 in the RLR group) were included in the study. The LLR group still had significantly higher intraoperative blood loss (100.0 ml vs. 50.0 ml, $p = 0.002$), postoperative complication rate (16 [19.8%] vs. 7 [8.6%], $p = 0.043$), postoperative hospital stay (6.0 days vs. 5.0 days, $p = 0.005$), and total hospital stay (12.0 days vs. 10.0 days, $p < 0.001$) compared to the RLR group, with no significant differences in the remaining indicators (all $p \geq 0.05$) (Table 2).

Table2 — Outcomes Of The Llr And Rlr Groups Before And After Psm

Outcomes	before PSM (n=277)			after PSM (n=162)		
	LLR (n = 175)	RLR (n = 102)	p value	LLR (n=81)	RLR (n=81)	p value
Operation time (IQR), min	168.0 (125.0-240.0)	165.0 (110.0-220.0)	0.263	180.0(120.0-250.0)	160.0 (107.5-220.0)	0.134
Status of surgical margins, n(%)			0.464			1
R0	172(98.3)	98(96.1)		80(98.8)	79(97.5)	
R1 or R2	3(1.7)	4(3.9)		1(1.2)	2(2.5)	
Intraoperative blood loss (IQR), mL	100.0 (50.0-400.0)	50.0 (50.0-112.5)	**<0.001**	100.0 (50.0-275.0)	50.0 (50.0-125.0)	**0.002**
Intraoperative blood transfusion, n(%)	33(18.8)	10(9.8)	**0.045**	12(14.8)	8(9.8)	0.339
Postoperative complications, n(%)	35(20.0)	7(6.8)	**0.003**	16(19.8)	7(8.6)	**0.043**
ClavienDindo classfication, n(%)			**0.006**			0.062

No	140(80.0)	95(93.1)		65(80.2)	74(91.4)	
I or II	25(14.3)	6(5.9)		10(12.3)	6(7.4)	
III or IV or V	10(5.7)	1(1.0)		6(7.4)	1(1.2)	
Conversion to open surgery during operation, n(%)	20(11.4)	0(0.0)	**0.001**	5(6.2)	0(0.0)	0.069
Reoperation during hospitalization, n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/
Perioperative mortality, n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/
Postoperative hospital stay (IQR), day	6.0(4.0-7.0)	5.0(3.8-6.2)	**0.001**	6.0(4.0-7.0)	5.0(3.5-6.0)	**0.005**
Readmission within 30 days postoperatively due to complications, n(%)	3(1.7)	1(1.0)	1	2(2.5)	1(1.2)	1
Total hospital stay (IQR), day	13.0 (10.0-16.0)	9.5(7.0-13.0)	**<0.001**	12.0 (10.0-16.0)	10.0(8.0-12.0)	**<0.001**
Total hospitalization cost (IQR), ¥	57150.9 (44313.0-76302.3)	81432.5 (74644.9-90934.2)	**<0.001**	58643.8 (45171.2-75899.8)	82885.3 (75617.3-90501.2)	**<0.001**
Out-of-pocket cost (IQR), ¥	16875.0 (9911.2-23013.9)	50333.4 (46274.6-57632.8)	**<0.001**	15972.7 (8999.7-23056.8)	50706.2 (46796.8-57640.6)	**<0.001**
Drug cost (IQR), ¥	15879.4 (11219.3-23459.2)	9955.6 (7687.4-14007.0)	**<0.001**	16517.6 (11994.0-24028.5)	9975.0 (7861.8-14117.4)	**<0.001**
Surgical cost (IQR), ¥	6916.0 (6302.0-7834.3)	43424.9 (42808.6-43897.9)	**<0.001**	6616.0 (6165.0-7481.4)	43424.9 (42754.1-43994.5)	**<0.001**
Examination cost (IQR), ¥	1260.0 (930.0-2153.0)	1160.0 (673.0-1752.8)	**0.010**	1365.0 (1075.0-2340.0)	1115.0 (659.0-1602.0)	**0.001**
Nursing cost (IQR), ¥	1164.0 (879.0-1521.0)	989.6 (784.0-1291.3)	**0.004**	1174.0 (832.5-1555.0)	988.6 (779.9-1255.1)	**0.012**
Consumables cost (IQR), ¥	21113.4 (15486.0-31411.4)	12094.4 (10839.8-18034.8)	**<0.001**	21565.4 (15899.2-32842.0)	12069.4 (10898.8-19094.2)	**<0.001**
Other cost (IQR), ¥	386.0 (182.0-722.0)	486.5 (246.5-851.8)	0.054	341.0(182.0-683.4)	535.0 (276.5-863.0)	**0.004**

C. cost outcomes of the patients

Before PSM, the LLR group had significantly lower total hospitalization cost (57,150.9 ¥ vs. 81,432.5¥, p < 0.001), out-of-pocket cost (16,875.0 ¥ vs. 50,333.4 ¥, p < 0.001), and surgical cost (6,916.0 ¥ vs. 43,424.9 ¥, p < 0.001) compared to the RLR group. However, the LLR group had significantly higher medication cost (15,879.4 ¥ vs. 9,955.6 ¥, p < 0.001), examination cost (1,260.0 ¥ vs. 1,160.0 ¥, p = 0.010), nursing cost (1,164.0 ¥ vs. 989.6 ¥, p = 0.001), and consumable cost (21,113.4 ¥ vs. 12,094.4 ¥, p < 0.001).

After balancing baseline characteristics through PSM, a total of 162 patients (81 in the LLR group and 81 in the RLR group) were included in the study. The LLR group still had significantly lower total total hospitalization cost (58,643.8 ¥ vs. 82,885.3 ¥, $p < 0.001$), out-of-pocket expense (15,972.7 ¥ vs. 50,706.2 ¥, $p < 0.001$), surgical cost (6,616.0 ¥ vs. 43,424.9 ¥, $p < 0.001$), and other cost (341.0 ¥ vs. 535.0 ¥, $p = 0.004$) compared to the RLR group. However, the LLR group had significantly higher medication cost (16,517.6 ¥ vs. 9,975.0 ¥, $p < 0.001$), examination cost (1,365.0 ¥ vs. 1,115.0 ¥, $p = 0.010$), nursing cost (1,174.0 ¥ vs. 988.6 ¥, $p = 0.001$), and consumable cost (21,565.4 ¥ vs. 12,069.4 ¥, $p < 0.001$) compared to the RLR group (Table 2).

D. outcomes of subgroup analysis

Subgroup analysis using the IWATE surgical difficulty classification as a covariate showed that in the "Low," "Intermediate," and "Advanced" subgroups, the total hospitalization cost for the LLR group were significantly lower than those for the RLR group (Low: 46,125.7 ¥ vs. 76,647.9 ¥, $p < 0.001$; Intermediate: 52,692.8 ¥ vs. 76,428.8 ¥, $p = 0.003$; Advanced: 67,548.3 ¥ vs. 84,725.0 ¥, $p = 0.001$). However, in the "Expert" group, there was no significant difference in total hospitalization cost between the LLR and RLR groups (75,709.0 ¥ vs. 88,292.6 ¥, $p = 0.325$) (Figure 2).

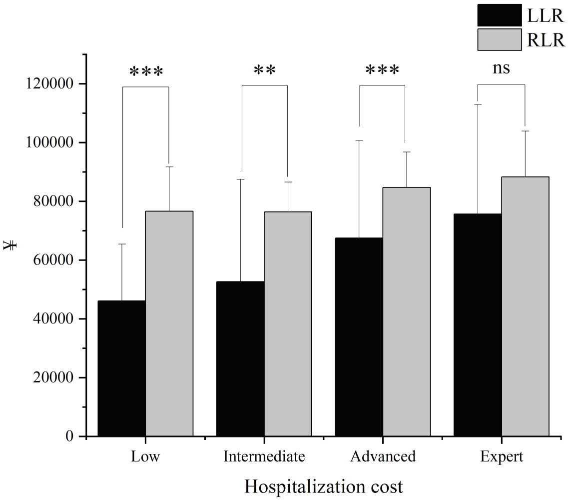

FIGURE2. SUBGROUP ANALYSIS OF TOTAL HOSPITALIZATION COST BASED ON SURGICAL DIFFICULTY

***: $p < 0.001$

**: $p < 0.005$

ns: $p > 0.05$

Combining patients with “Low” and “Intermediate” IWATE surgical ratings into a low surgical difficulty group, and those with “Advanced” and “Expert “ IWATE surgical ratings into a high surgical difficulty group, a subgroup analysis was performed. The results showed that in both surgical difficulty subgroups, the LLR group had significantly higher intraoperative blood loss (low surgical difficulty: 100.0 (50.0-200.0) vs. 50.0 (20.0-150.0) mL, p=0.013; high surgical difficulty: 200.0 (80.0-400.0) vs. 100.0 (50.0-137.5) mL, p=0.024), longer postoperative hospital stay (low surgical difficulty: 5.0 (4.0-7.0) vs. 4.0 (3.0-5.5) days, p=0.010; high surgical difficulty: 6.5 (5.0-9.0) vs. 5.0 (4.0-7.0) days, p=0.046), and longer LOS (low surgical difficulty: 12.0 (9.0-16.0) vs. 10.0 (7.0-12.0) days, p=0.005; high surgical difficulty: 13.5 (10.0-16.0) vs. 9.5 (8.0-12.0) days, p<0.001) compared to the RLR group. There were no significant differences between the LLR and RLR groups in other outcome indicators in either surgical difficulty subgroup. (Table 3)

TABLE 3 — ANALYSIS OF CLINICAL OUTCOME INDICATORS FOR IWATE SURGICAL DIFFICULTY SUBGROUPS

Outcomes						
	Low + Intermediate (n = 86)			Advanced + Expert (n = 76)		
	LLR (n = 45)	RLR (n = 41)	p value	LLR (n=36)	RLR (n=40)	p value
Operation time (IQR), min	155.0 (100.0-223.8)	120.0 (85.0-180.0)	0.228	195.0 (164.0-260.0)	187.5 (150.0-240.0)	0.265
Status of surgical margins, n(%)			/			1
R0	45(100.0)	41(100.0)		35(97.2)	38(95.0)	
R1 or R2	0(0.0)	0(0.0)		1(2.8)	2(5.0)	
Intraoperative blood loss (IQR), mL	100.0 (50.0-200.0)	50.0 (20.0-150.0)	**0.013**	200.0 (80.0-400.0)	100.0 (50.0-137.5)	**0.024**
Intraoperative blood transfusion, n(%)	7(15.6)	3(7.3)	0.393	5(13.8)	5(12.5)	1
Postoperative complications, n(%)	8(17.8)	3(7.3)	0.147	8(22.2)	4(10.0)	0.145
ClavienDindo classfication, n(%)			0.063			0.341
No	37(82.2)	38(92.7)		28(78.8)	36(90.0)	
I or II	4(8.9)	3(7.3)		6(16.7)	3(7.5)	
III or IV or V	4(8.9)	0(0.0)		2(5.6)	1(2.5)	
Conversion to open surgery during operation, n(%)	3(6.7)	0(0.0)	0.274	2(5.6)	0(0.0)	0.428
Reoperation during hospitalization, n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/
Perioperative mortality, n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/
Postoperative hospital stay (IQR), day	5.0 (4.0-7.0)	4.0(3.0-5.5)	**0.010**	6.5(5.0-9.0)	5.0(4.0-7.0)	**0.046**

Readmission within 30 days postoperatively due to complications, n(%)	2(4.4)	1(2.4)	1	0(0.0)	0(0.0)	/
LOS (IQR), day	12.0 (9.0-16.0)	10.0 (7.0-12.0)	**0.005**	13.5 (10.0-16.0)	9.5 (8.0-12.0)	**<0.001**

IV. Discussion

In recent years, liver surgery has developed rapidly. Compared with open surgery, LLR surgery offers better safety, similar oncological outcomes, and comparable costs. Over the past decade, it has become the primary minimally invasive surgical option for patients with benign and malignant liver lesions. However, the use of LLR in patients with HCC located in challenging positions and requiring complex procedures is limited by factors such as unstable video views and the rigidity of laparoscopic instruments. The introduction of RLR has overcome the inherent limitations of traditional LLR, offering more flexible and precise operations. This advantage is particularly evident in complex and extensive liver cancer resections, providing patients with better short-term outcomes. Nevertheless, the higher surgical costs associated with RLR remain a significant constraint on its development. The cost-effectiveness of RLR continues to be a matter of debate.

Currently, there are few studies comparing the medical costs of robotic versus laparoscopic liver resections, both domestically and internationally. This study investigates the clinical value and medical expenses of using medical robots versus laparoscopes for HCC resection, providing evidence-based medicine to inform surgical treatment strategies for HCC patients. Additionally, this study is the first to explore the cost-effectiveness of RLR across different surgical difficulties using the IWATE difficulty scoring system for liver resection. This helps physicians choose the most appropriate surgical approach based on the health economics benefits of varying surgical complexities. Given the significant variability in robotic surgery costs across different centers in real-world settings, patients in this study were selected from the same medical institution and treated by the same medical team to minimize intergroup differences. Furthermore, consistent surgical performance by the primary surgeon also reduced the impact of surgical skill on patient outcomes. To eliminate the influence of baseline characteristics on the study results, PSM was used to minimize bias. The PSM results showed no significant differences in baseline indicators between the LLR and RLR groups (all $p \geq 0.05$).

To investigate whether RLR is cost-effective compared to LLR, we compared the differences in clinical outcomes and cost indicators between the two groups after PSM. The results showed that the two groups were similar in terms of operation time, surgical margin status, intraoperative blood transfusion, conversion to open surgery, and 30-day readmission due to complications. However, the LLR group had significantly higher intraoperative blood loss, postoperative complication rates, length of hospital stay, and postoperative hospital stay compared to the RLR group, demonstrating that RLR is superior to LLR in terms of surgical safety. In terms of costs, the total hospitalization costs and out-of-pocket costs were significantly lower in the LLR group than in the RLR group, further corroborating the higher expenses required for RLR compared to LLR. Considering the composition of total hospitalization costs, we found that the surgical costs in the LLR group were significantly lower than those in the RLR group. However, the costs for medication, examinations, nursing, and consumables were significantly higher in the LLR group compared to the RLR group. This suggests that the high surgical costs are the main reason for the significantly higher total hospitalization costs in the RLR group compared to the LLR group. Nonetheless, RLR improves patient outcomes by reducing the need for postoperative medication and further examinations, thus lowering other expenses for patients. Therefore, we believe that although the total costs of RLR are higher than those of LLR, patients undergoing RLR achieve better clinical outcomes and incur fewer expenses outside of surgery. In the future, by reducing the surgical costs of RLR, it will become more cost-effective.

Relevant studies have indicated that the high surgical costs of robotic surgery mainly stem from the usage costs of the robotic system itself, as well as the costs of maintenance and disposable supplies. This aligns with the experience of our research center, where the startup costs of the robot account for the majority of surgical expenses in robotic surgeries. However, considering the continuous use of the robotic system, adjustments in medical insurance for surgical robots, and the competition introduced by other robotic manufacturers in the future, it is expected that these costs will gradually decrease over time, leading to an increased use of RLR in liver surgery.

Numerous studies have indicated that RLR is superior to LLR in patient populations with high surgical difficulty. At the same time, higher surgical difficulty often demands higher medical expenses. This study has found that the total hospitalization costs for RLR are significantly higher than those for LLR. However, is there a difference in the cost disparity between RLR and LLR among patients with varying levels of surgical difficulty? To investigate this issue, this study defined patient surgical difficulty based on the IWATE surgical difficulty classification and further conducted subgroup analysis with surgical difficulty as a covariate. Results showed that in the “Low,” “Intermediate,” and “Advanced” subgroups, the total hospitalization costs for the LLR group were significantly lower than those for the RLR group. However, in the “expert difficulty” subgroup, there was no significant difference in total hospitalization costs between the LLR and RLR groups (75709.0(64022.6-101275.4) vs. 88292.6(82954.8-98554.0) ¥, p=0.325). Therefore, we believe that as surgical difficulty increases, the cost difference between RLR and LLR decreases. Further comparison of clinical indicators between RLR and LLR within each surgical difficulty subgroup showed that, regardless of the subgroup, the LLR group had significantly higher intraoperative blood loss, postoperative hospital stay, and LOS compared to the RLR group, with no significant differences in other outcome indicators between the two groups. This suggests that RLR’s clinical outcomes are comparable to those of LLR, regardless of surgical difficulty. Therefore, combining the reduced cost gap between the two surgical methods with increasing surgical difficulty, this study concludes that for higher difficulty HCC resection surgeries, RLR is a better choice compared to LLR.

This study also has certain limitations. First, patients were selected from a single center and a single medical team. Given the variations in robotic surgery costs across different centers, our results may not be generalizable to other medical institutions. The technical proficiency of the surgeon can also impact the cost-effectiveness of the surgery, which is why we selected patients operated on by the same lead surgeon within a single medical team. However, this also limits the applicability of our findings to other medical teams. Secondly, in current health economic evaluations, particularly when assessing new drugs, treatments, diagnostic tools, or public health interventions, cost-effectiveness analysis (CEA) is commonly used. CEA often incorporates quality-adjusted life years (QALY) to evaluate patient quality of life, ultimately using cost and QALY to calculate the cost required to improve a unit of QALY, thus assessing the cost-effectiveness of the intervention. However, this study is a retrospective study and did not prospectively evaluate the postoperative quality of life of patients. Additionally, the outcome indicators used in this study are short-term outcomes, so QALY was not calculated, and the cost-effectiveness of patients could not be assessed. Lastly, the study did not include the cost of purchasing the robot as an indirect cost in the analysis. This was mainly because the laparoscopic equipment, used as a comparison, was purchased earlier, and the purchasing power at different times is not directly comparable. Furthermore, the cost of purchasing the robot varies among different centers.

V. Conclusion

This study demonstrates that for patients with HCC, RLR offers better surgical safety but incurs relatively higher medical costs compared to LLR. However, RLR results in lower non-surgical costs. Additionally, as the surgical difficulty increases, the cost difference between the two procedures decreases, making RLR a better choice for HCC patients with high surgical difficulty.

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Mid-term Follow-up Study on Robot-assisted Total Knee Arthroplasty and Traditional Knee Arthroplasty

BY BEINI LYU YANG SONG AND YIXIN ZHOU*

Knee joint disease imposes a substantial health burden in China, with total knee arthroplasty (TKA) being the most effective treatment for end-stage knee osteoarthritis. Compared to traditional TKA, robot-assisted TKA is expected to enhance patient outcomes. However, its superiority in terms of postoperative joint function, pain relief, stiffness, patient satisfaction, and overall health scores remains inconclusive, particularly due to the lack of follow-up studies based on Chinese patient data. The current study included 202 patients who underwent robot-assisted TKA at a single center, matched 1:1 with patients who underwent traditional TKA, and followed up on their mid-term clinical outcomes and efficacy indicators. Baseline characteristics were similar between the two groups. One patient in the robot-assisted TKA group required revision surgery due to postoperative hyperextension, while no revisions were recorded in the traditional TKA group. Other prosthesis-related complications, joint-related hospitalizations, surgeries, outpatient visits, and postoperative joint satisfaction showed no significant differences. Additionally, the two groups exhibited no significant differences in joint function scores (WOMAC scores) and quality of life scores. Compared to traditional surgery, the robot-assisted surgery group had a longer operation time (96.61 minutes vs.

Lyu: Institute for Global Health and Development, Peking University, Beijing, 100080 (email: blyu@pku.edu.cn); Song & Zhou: Beijing Jishuitan Hospital, Capital Medical University, Beijing, 102208. Acknowledgements: All authors declare no conflicts of interest. This study was supported by the Beijing Natural Science Foundation-Haidian Original Innovation Joint Fund (Grant No. L242168) and the SMART Parallel Research Grant from the Peking University Institute for Global Health and Development.

79.13 minutes), but the duration gradually decreased as the robotic procedure became more established ($p<0.05$). In summary, robot-assisted TKA and traditional TKA demonstrate similar mid-term clinical outcomes. This study will continue to assess economic costs and develop long-term economic models to further evaluate the cost-effectiveness of robot-assisted surgery compared to traditional surgery.

I. Introduction

Total knee arthroplasty (TKA) is the most effective treatment for end-stage knee osteoarthritis, providing patients with a comfortable and stable artificial knee joint (Kim et al., 2020). Since the 1970s, advancements in artificial joint materials, biomechanics, biochemistry, and perioperative management have significantly improved surgical techniques, prosthesis types, expected lifespans, and patient satisfaction. Compared to traditional manual cutting tools, robot-assisted TKA offers enhanced precision in localization, accurate bone cutting, and personalized prosthesis implantation (Shao et al., 2023; Subramanian et al., 2019; Yang et al., 2024). However, the superiority of robot-assisted TKA over traditional TKA in terms of postoperative joint function, pain relief, stiffness, satisfaction, and overall health scores remains uncertain. Studies comparing the two surgeries often have small sample sizes and short follow-up durations, particularly lacking research based on Chinese patient data.

This study includes all patients who underwent robot-assisted TKA at our center over the past three years, matched with patients who underwent traditional TKA during the same period. Using a combination of retrospective study and prospective follow-up, we aimed to examine the differences in mid-term clinical outcomes between robot-assisted and traditional TKA.

II. Methods

Patients were recruited from the Department of Orthopedic Surgery, Beijing Jishuitan Hospital, Capital Medical University, between February 2022 and March 2024. Inclusion criteria included: age 21-80 years, consent to participate in the study, and eligible for unilateral TKA. Exclusion criteria included pregnancy, revision knee surgery, severe flexion (>20°) or valgus/varus deformities (>20°), poor bone quality preventing prosthesis implantation, presence of metal implants in the surgical area, active infections, allergies to implant materials, hip disorders, neuromuscular disorders, severe systemic diseases, or chronic pain conditions requiring long-term analgesics.

Patients were matched 1:1 based on age, sex, and surgery date (±3 months) with those undergoing traditional TKA. The study was approved by the hospital's ethics committee, and all patients provided informed consent.

The robot-assisted TKA group underwent surgery using the TIANVI 2.0 robot (Tianzhihang, China) or the MAKO robot (Stryker, USA), with cemented CR or PS prostheses from brands including Triathlon (Stryker, USA) and Legion (Smith & Nephew, UK). The traditional TKA group underwent manual surgery using femoral intramedullary and tibial extramedullary alignment, with cemented CR or PS prostheses from Triathlon, Legion, and GT (AK Medical, China). Surgical approaches, anesthesia, perioperative pain management, postoperative antibiotic regimens, and rehabilitation protocols were consistent between groups.

Patient demographics and clinical data, including age, sex, BMI, preoperative diagnosis, comorbidities, surgical laterality, ASA scores, and preoperative joint function scores, were collected from electronic medical records. Joint function was assessed using the Western Ontario and McMaster Universities Arthritis Index (WOMAC) score, which includes total score and sub-scores for pain, stiffness, and function. Surgery-related data, such as operation time, intraoperative blood loss, and postoperative complications, were also recorded. Follow-up was conducted via telephone between October and November 2024, assessing overall satisfaction, joint function, and quality of life using the EQ-5D-5L questionnaire. Preoperative EQ-5D-5L scores were retrospectively collected.

Statistical Analysis: Continuous variables were presented as mean (standard deviation) for normally distributed data or median (interquartile range) for non-normally distributed data, and analyzed using two-tailed t-tests. Categorical variables were presented as frequency (percentage) and analyzed using Chi-square or Fisher's exact tests. Changes in WOMAC and EQ-5D-5L scores were calculated, and utility values and quality-adjusted life years (QALYs) were derived using the established Chinese population utility scoring system (Liu et al., 2014). Analyses were conducted using R software (www.R-project.org), with statistical significance defined as two-sided $p<0.05$.

III. Results

During the study period, 247 patients underwent robot-assisted TKA and were matched with 247 patients who underwent traditional TKA. Follow-up was completed for 202 (81.8%) robot-assisted and 199 (80.6%) traditional TKA patients, with no significant difference in follow-up rates. The median follow-up duration was 18 (7-31) months.

Baseline characteristics showed no significant differences between groups (Table 1). However, operation time was significantly longer in the robot-assisted group (96.61 minutes vs. 79.13 minutes, p<0.001).

Table 1. Baseline and interoperative characteristics of patients in robot-assisted and traditional groups

	Robot-assisted （n=202)	Traditional (n=199)	P value
Age, years	66.94 (6.60)	66.96 (6.34)	0.96
Female	166 （82.18)	163 (81.91)	1.0
Knee osteoarthritis	202	199	1.0
Surgery side, left	95 （47.03)	97 (48.74)	0.81
BMI, kg/m^2	28.29 (12.71)	26.60 (3.32)	0.072
Hypertension	88 （43.56)	99 (49.75)	0.40
Cardiovascular disease	21 （10.40)	5 (2.51)	0.005
Diabetes	28 （13.86)	34 (17.09)	0.55
ASA, class 1	70 （34.65)	71 (17.09)	0.60
Surgery duration, minutes	96.61 (20.50)	79.13 (18.65)	<0.001
Blood loss, mL	56.35 (31.50)	56.26 (33.99)	0.98

Notes: BMI, body mass index; ASA, American Society of Anesthesiologists.

One patient in the robot-assisted group required revision surgery for hyperextension, while no revisions occurred in the traditional group (Table 2). There was no significant difference in other surgery-related complications, hospitalizations, and outpatient visits.

Table 2. Prosthesis and joint-related outcomes in robot-assisted and traditional surgery groups

	Robot-assisted(n=202)	Traditional (n=199)	P value
Prosthesis revision	1 (0.50)	0	1.0
Prosthesis loosening	0	0	NA
Prosthesis infection	1(0.50)	0	1
Joint-related hospitalization	4(1.98)	0	0.14
Joint-related surgery	4(1.98)	0	0.14
Joint-related outpatient visits	12(5.94)	10(5.03)	0.56

We found similar postoperative satisfaction rates (robot-assisted: 88.62% vs. traditional: 88.44%, p=0.32, Table 3). However, three patients in the robot-assisted group reported being "very dissatisfied," whereas none in the traditional group did.

Table 3. Postoperative satisfaction rate in robot-assisted and traditional surgery groups

	Robot-assisted(n=202)	Traditional (n=199)	P value
Satisfaction			0.32
Very satisfied	112 (55.45)	125 (62.81)	
Satisfied	67 (33.17)	51 (25.63)	
Neutral	15 (7.43)	19 (9.55)	
Dissatisfied	5 (2.47)	4 (2.01)	
Very dissatisfied	3 (1.49)	0	

Preoperative and follow-up WOMAC scores of patients undergoing robot-assisted and traditional surgery were presented in table 4. There were no significant differences in overall WOMAC scores, as well as pain, stiffness, and functional scores between the two groups before surgery (p>0.05 for all). After surgery, both groups showed significant improvement in overall and subcategory WOMAC scores, but the differences between the two groups were not statistically significant (p >0.05 for all). We further examined the average WOMAC scores by follow-up months and found similar patterns between the two groups (Figure 1).

Table 4. WOMAC score in robot-assisted and traditional surgery groups

	Robot-assisted(n=202)	Traditional (n=199)	P value
Overall WOMAC score			
Preoperational	45.40 (20.72)	45.99 (19.98)	0.77
Follow-up	7.21 (11.11)	6.38 (10.63)	0.44
Difference	38.18 (21.52)	39.61 (19.88)	0.49
WOMAC pain			
Preoperational	54.48 (24.71)	52.46 (23.79)	0.41
Follow-up	6.56 (12.28)	5.98 (11.64)	0.63
Difference	47.92 (25.24)	46.48 (24.33)	0.56
WOMAC stiffness			
Preoperational	32.80 (29.94)	34.17 (28.52)	0.64
Follow-up	7.43 (15.08)	6.85 (13.63)	0.69
Difference	25.37 (31.34)	27.32 (29.03)	0.52
WOMAC function			
Preoperational	44.21 (21.45)	45.48 (20.83)	0.55
Follow-up	7.38 (12.12)	6.44 (11.33)	0.42
Difference	36.82 (22.48)	39.04 (20.93)	0.31

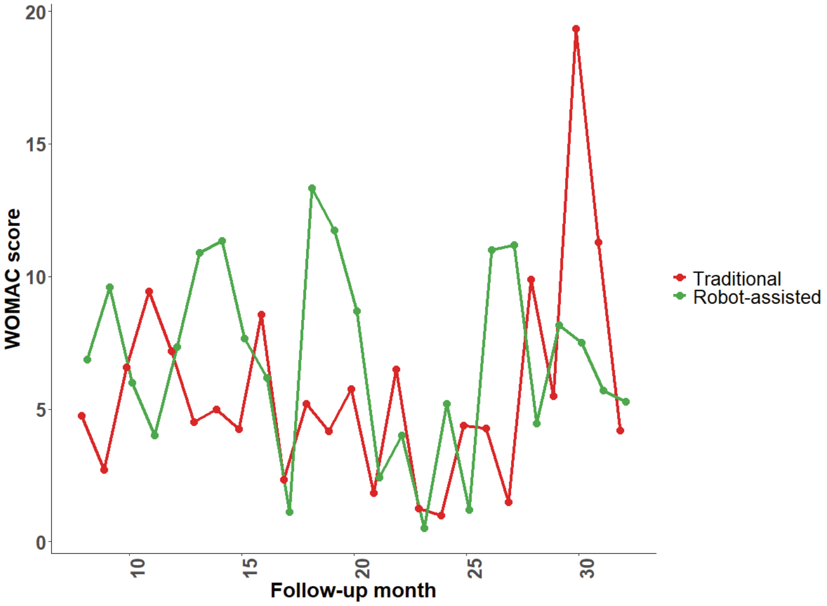

Figure 1. Changes in WOMAC scores after surgery in robot-assisted and traditional surgery groups

Subgroup Analysis: Considering the learning curve of robot-assisted surgery, we further conducted a stratified analysis of the surgical duration for both surgeries based on follow-up time. The results showed that the operation time in the traditional surgery group remained similar regardless of follow-up duration (p>0.05). However, in the robot-assisted surgery group, as follow-up duration shortened, indicating a longer period since the adoption of robotic surgery, the overall operation time significantly decreased (p<0.05, Table 5). For patients with a follow-up duration of 8-12 months, the operation time required for robot-assisted surgery was no longer significantly different from that of traditional surgery (p=0.094). The specific trend of surgical duration over time for both groups was illustrated in Figure 2.

Table 5. Operation time (minutes) across different follow-up time in robot-assisted and traditional surgery group

	Robot-assisted (n=202)	Traditional (n=199)	P value
Post operation follow-up months,			0.32
8-12	93.82 (14.83)	85.41 (24.48)	0.094
12-16	95.66 (18.14)	79.57 (19.72)	<0.001
16-20	87.11 (15.81)	77.04 (13.69)	0.019

20-24	99.77 (25.33)	78.96 (13.20)	<0.001
24-28	90.56 (22.42)	76.64 (15.47)	0.013
≥28	111.84 (20.37)	77.79 (20.21)	<0.001

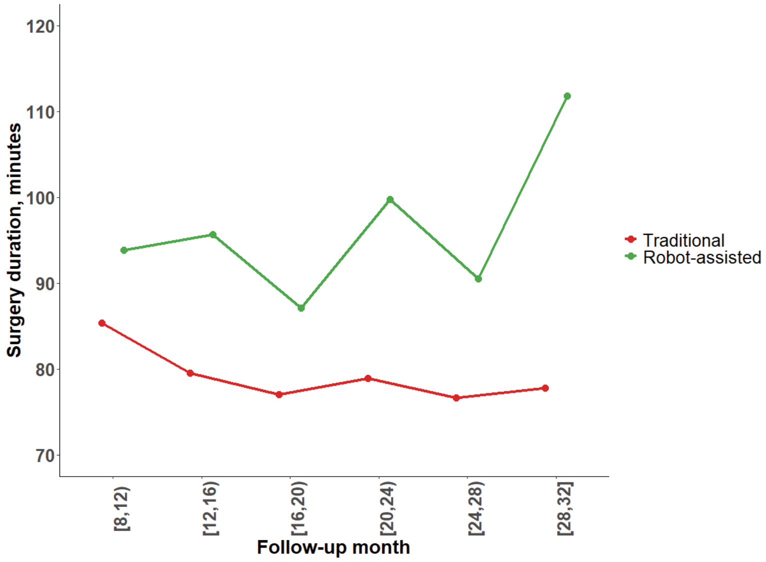

Figure 2. Trend of surgical duration over follow-up time in robot-assisted and traditional surgery groups

IV. Summary

As a single-center cohort study combining retrospective and prospective analyses, we found that the mid-term clinical outcomes of robot-assisted TKA were comparable to those of traditional surgery. With advancements in robotic technology, the duration of robot-assisted procedures has gradually decreased.

Previous studies suggested that robot-assisted TKA allows for more precise prosthesis implantation compared to manual TKA. Radiographic assessments indicate that the postoperative alignment of the femoral and tibial prostheses in robot-assisted TKA is closer to the preoperative design than that achieved through manual implantation. Additionally, previous studies have reported longer surgical durations for robot-assisted procedures compared to traditional ones, which aligns with our findings. The extended surgical duration may be attributed to the introduction of new instruments, the need for additional robotic control personnel, the time required for robotic setup and calibration, and the coordination among multiple surgical team members. However, the total procedure time for robotic surgery did not exceed 120 minutes, suggesting that it does not theoretically increase the risk of infection. Moreover, we observed that as robotic surgery became more established and the procedure volume increased, the time difference between robotic and traditional surgery gradually diminished. In the past year, although the robotic group still had slightly longer operation times, the difference was no longer statistically significant.

We found no significant differences between robot-assisted and traditional surgery in terms of WOMAC scores, quality of life, and overall patient satisfaction with joint replacement. This finding is consistent with most previous studies. Some research suggests that in the early postoperative period (<6 months), robot-assisted surgery may provide better pain relief and functional recovery due to reduced soft tissue disruption and lower periarticular inflammation. However, since the shortest follow-up period in our study was seven months, early postoperative outcomes were not analyzed. Based on our mid-term follow-up results, robot-assisted and manual TKA demonstrated similar clinical efficacy.

Notably, our study included the earliest patients who underwent robot-assisted surgery at our center, meaning that surgeons had to navigate the learning curve associated with this new technology. Meanwhile, the control group consisted of patients operated on by highly experienced surgeons who had performed over 450 cases per year and had more than ten years of experience in manual TKA. This may partially explain why there were no significant differences in clinical outcomes between the two groups. Manual TKA requires extensive experience and a prolonged learning curve. By using robotic assistance, surgeons may achieve clinical results comparable to those of highly skilled manual TKA surgeons within a shorter time, significantly reducing the learning curve. Our study observed that as robotic technology became more widely used, operation times in the robotic group decreased rapidly. Whether robot-assisted TKA will continue to improve surgical efficiency and clinical outcomes compared to traditional surgery requires further investigation.

This study has several limitations. First, the WOMAC scores were subjective assessments provided by patients during phone follow-ups. Responses may have been influenced by the patients' environment at the time of the survey, and some patients provided unclear answers, potentially affecting the results. Second, the follow-up rate was 81.8%, which may introduce a survivorship bias. Lastly, part of this study was retrospective in design, which inherently carries the risk of researcher bias affecting the follow-up outcomes.

In conclusion, our study found no significant differences in postoperative clinical outcomes or patient satisfaction between robot-assisted and manual TKA. Additionally, as robot-assisted surgery became more widely adopted, its overall operation time approached that of conventional manual TKA. These findings suggest that robot-assisted TKA may enhance surgical efficiency in the short term and help mitigate the long learning curve associated with traditional surgery. Future research will continue to assess the economic costs and develop long-term models to further evaluate the cost-effectiveness of robot-assisted versus traditional surgery.

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AI and Career Barriers in Surgery Departments: Research Progress

By Yuhang Pan Junjian Yi AND Qingyuan Zhou *

I. Baseline Results

In this section, we present our main findings, showing the effect of the introduction of da Vinci robots on gender composition in surgical departments.

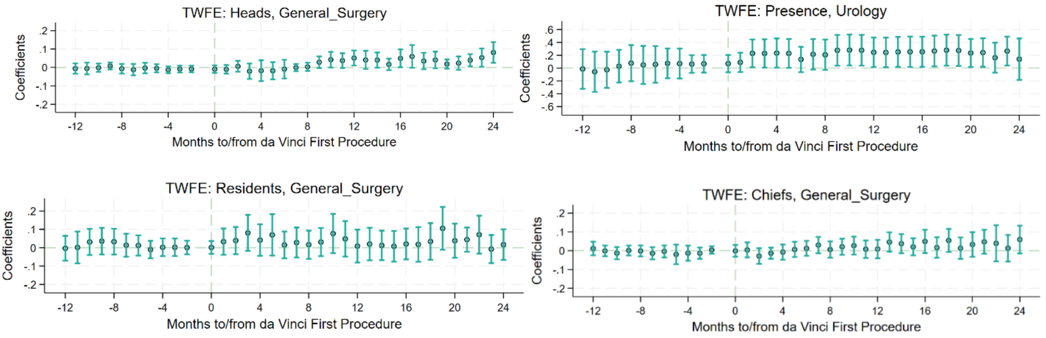

Figure 1. Months to/from da Vinci First Procedure and Female Presence

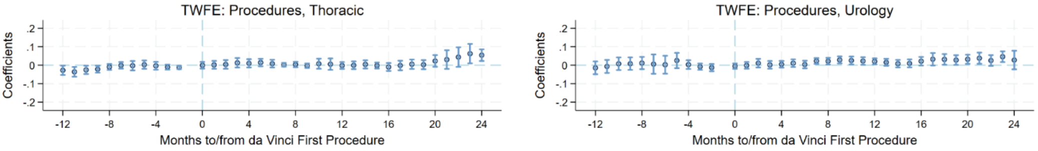

Figure 2. Months to/from da Vinci First Procedure and Female Workloads

Figure 1 depicts the changes in female presence and ratio of female heads, chiefs, residents and attendings across various departments over time. We use the difference between the treated and control hospital-departments one month before the introduction of the robots as the reference group. We find that in the months following the introduction of the da Vinci surgical system, the relative presence of females increases in departments of urology and general surgery, while remaining relatively stable in others. Additionally, in the department of general surgery, proportions of female heads and chiefs increase,

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* Authors contribute equally and are ranked in alphabetical order. Pan: Institute for Global Health and Development, Peking University (email: yhpan@pku.edu.cn); Yi: National School of Development and Institute for Global Health and Development, Peking University (email: junjian@nsd.pku.edu.cn); Zhou: School of Economics, Peking University (email: qingyuanzhou.econ@gmail.com). All errors are our own.

indicating more promotion opportunities for females. However, these changes do not occur immediately after the adoption of robots, possibly because it takes time to make personnel adjustments.

Figure 2 illustrates trends in female workloads across different departments. It reveals that after the technology adoption, departments of thoracic and urology experience an increase in the volume of procedures performed by female surgeons. This provides evidence that skill-biased technological changes could alter the comparative advantage between males and females and facilitate greater female participation and entry into surgery departments.

II. Work in progress

The evidence in the previous section suggests increasing presence and opportunities for promotion of females in some departments. This section examines mechanisms related to this narrowing gender gap. Specifically, we employ case-level and physician-level data to estimate the impact of da Vinci robot adoption on physicians' decisions concerning resource utilization and patient health outcomes by gender.

A. case-level evidence on physician productivity by gender

Outcome Variables. To measure medical resource use, we include two primary outcomes: (i) the patient length of stay (i.e., the date between patient assignment to the provider and patient discharge), (ii) fees spent on tests and exams performed on the patient and (iii) the total cost of care during the current hospital stay. To mitigate the effect of extreme values, we take log of the medical spending. To measure quality of care, we examine two prominent patient outcomes: (i) indicators of patient 30-day inpatient readmission—whether the patient is rehospitalized within 30 days of the discharge and (ii) indicators of patient in-hospital mortality.

Control Variables. Our specification also includes a vector of patient covariates, including indicators for five-year age bins, gender and indicators for three-digit International Classification of Diseases, Tenth revision (ICD-10) codes of patient's primary diagnosis of the visit.

Our empirical specification takes the following form:

$$(1)\ Y_{ijt} = \sum_{k=-12, k\neq -1}^{k=24} \beta_k MR_{jt,k} + X_i\gamma + \delta_j + \eta_t + \xi_{jt}$$

where the Y_{ijt} denotes measures of medical resource use and quality of care for case i in hospital-department j and month-year t. $MR_{jt,k}$ represents dummy variables that equal 1 if in month-year t, there are months before(after) the first robotic-assisted procedure in hospital-department j, and 0 otherwise. X_i denotes patient risk adjusters. We also include hospital-department fixed effect δ_j and month-year fixed effect η_t. ϵ_{jt} is the idiosyncratic error term. We cluster standard errors by hospital-department.

B. physician-level evidence on physician productivity by gender

To investigate why female surgeons have more promotion opportunities after the introduction of robots, we assess the extent to which robot adoption alter surgeons' productivity separately for males and females.

We adopt the following specification to estimate the causal effect of the physician's use of robots on his/her productivity and workloads:

$$(2)\ Y_{it} = \sum_{k=-12,k\neq -1}^{k=24} \beta_k MR_{it,k} + \delta_i + \eta_t + \xi_{it}$$

where subscript i denotes a physician and t denotes the quarter-year. The dependent variable Y_{it} represents in-hospital death rate, 30-day inpatient readmission rate, average hospitalization days and average spendings of physician i's patients as well as total number of procedures of physician i in time t. The independent variables of interest $MR_{it,k}$ are dummy variables that equal 1 if in quarter-year t, there are k quarters before(after) physician i first conduct a surgery using da Vinci robot, and 0 otherwise. We include physician fixed effects δ_i to control for physician heterogeneities. That is, the estimation in equation (2) exploits within-physician variations. Finally, ϵ_{it} is the error term. Standard errors are clustered at physician level.

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

By Yin Shi Ziting Wu*

This study focuses on the impact of robotic surgery on the economic burden of pancreatic malignancies, falling within the scope of micro-costing research. Since the introduction of laparoscopic pancreaticoduodenectomy in 1994, the use of laparoscopic or robotic-assisted techniques in pancreatic surgery has garnered significant attention. However, there remains controversy regarding their oncological outcomes and surgical safety in the radical treatment of pancreatic cancer, and the economic benefits of robotic surgery are still unclear. Patient data, including demographic information, surgical details, pathological staging, and costs, were obtained through hospital discharge records and surgical logs. Variables were processed, such as conversion of residential information, CPI-adjusted in-hospital costs, and physician experience. Additionally, patient-related costs, such as transportation, accommodation, nutrition, and time, were collected through surveys. Data cleaning has been completed for 1,730 in-hospital cases, of which 42.3% were female, with an average age of 60.8 years, and 64% came from urban areas. Robotic surgery accounted for 56.2%, with significant differences in length of stay and costs between surgical types. Data cleaning for 74 out-of-hospital cases has also been completed, revealing that non-medical and indirect

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* Shi: Department of pharmacy, Xiangya Hospital Central South University, Changsha, Hunan, P.R. China, 410008 National Clinical Research Center for Geriatric Disorders, Xiangya Hospital, Central South University, Changsha, Hunan, P.R. China, 410008: Institute for Global Health and Development, Peking University, Beijing, China, 100871, (e-mail: shiyin910515@csu.edu.cn); Wu: Institute for Global Health and Development, Peking University, Beijing, China, 100871 (e-mail: wuziting@pku.edu.cn).

costs for robotic surgery patients were lower. The research team will continue to collect complete data to lay the groundwork for future analysis of the cost-effectiveness of robotic surgery in the treatment of pancreatic malignancies.

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

Through hospital discharge records and surgical logs, we obtained patient demographic characteristics, surgical details, pathological staging, and cost information. Specific variables include gender, age, marital status, contact address, admission date, department, discharge date, primary diagnosis, treatment outcome, attending physician, insurance type (urban employee/residential/ non-insured), surgery date, surgery start time, surgery end time, surgery type, surgery name, intraoperative blood loss, complications, pathological staging, total costs, bed fees, nursing fees, pharmaceutical costs, radiology fees, blood transfusion fees, consultation fees, surgical fees, laboratory fees, and other related variables. However, the variables obtained from the hospital require processing before statistical analysis. This includes converting contact addresses to urban, township, or rural locations to represent the patient's permanent residence, adjusting in-hospital costs using the Consumer Price Index (CPI) to reflect 2024 prices, and using the number of surgeries performed by each physician prior to the patient's surgery as a measure of the physician's experience.

The calculation method for China's CPI is as follows: (value of a fixed basket of goods at current prices / value of the same basket of goods at base period prices) × 100. The inflation rate is calculated as (current CPI - base period CPI) / base period CPI × 100%. Alternatively, the inflation rate can also be expressed as (current price level - base period price level) / base period price level × 100%. Therefore, the current price is calculated as: inflation rate × base period price level + base period price level. In this study, the current period is 2024, and the base period is 2013-2023. The specific inflation rates are shown in Table 1.

TABLE 1. INFLATION RATES IN CHINA FROM 2013 TO 2023

Year	CPI	Inflation Rates
2024	100.4	—
2023	100.2	0.001996008
2022	102	-0.015686275
2021	100.9	-0.004955401
2020	102.5	-0.020487805
2019	102.9	-0.024295432
2018	102.1	-0.016650343
2017	101.6	-0.011811024
2016	102	-0.015686275
2015	101.4	-0.009861933
2014	102	-0.015686275
2013	102.6	-0.021442495

Through surveys, we obtained information on patient-related costs during their medical treatment, including transportation fees, accommodation fees, family member accommodation or accompanying costs, patient nutrition costs, patient time costs (in days), family member time costs (in days), whether a caregiver was hired, and the caregiver's daily wage. In this study, the time costs for both patients and their family members were converted into monetary terms according to specific rules.

For caregivers below retirement age, the corresponding wage standards for the relevant population were used for calculation. Specifically, the average hourly wage for individuals with the same gender, age, and education level (Guo Lin, 2020) was applied. For unpaid housewives or retirees, whose hourly wage is often unknown, local time-value standards from time-use studies can be applied. For example, Hanly et al. (Hanly et al. 2013) employed three methods in their opportunity cost evaluation of time spent on informal caregiving for colorectal cancer: the first method did not consider the caregiver's employment status and calculated time costs based on the local average hourly wage; the second method calculated for employed caregivers based on hourly wages divided by industry and gender, while non-employed caregivers were calculated using the local minimum wage; the third method calculated for employed caregivers based on hourly wages divided by occupation and gender, with non-employed caregivers referenced to the local minimum wage.

In this study, specifically, if the patient or their family member was employed during the medical treatment, the calculation was based on the average hourly wage for urban workers in China in 2023. If they were unemployed or engaged in childcare or housework, the calculation was based on the national minimum wage standard as of October 2024.

The annual working hours calculation standard comes from the official website of the Chinese government. The method for calculating the number of working days is: 365 days - 104 days (rest days) - 13 days (public holidays) = 248 days. The total working hours are calculated by multiplying the number of working days in a month, quarter, or year by 8 hours per day.

The average annual wage of employed individuals is sourced from the National Bureau of Statistics. In 2023, the average annual wage for employees in urban non-private and private enterprises was ￥120,698 and ￥68,340, respectively, with an overall average of ￥94,519 RMB.

The monetary value of the time of employed patients or their family members per hour is calculated as follows: 94,519 / 248 / 8 = ￥47.6 /hour.

For unemployed individuals, the wage is calculated based on the national minimum wage standard. Data from the Ministry of Human Resources and Social Security of China indicates that the average national hourly minimum wage is ￥20 /hour, which was used in this study.

III. Results

A. Data Cleaning Results

Data for 1,730 in-hospital cases have been cleaned. Among these, 42.3% (732/1,730) were female, with an average age of 60.8 years (standard deviation: 9.4). 64% of the patients (1,108/1,730) were from urban areas.

Among the cases, 973 patients underwent robotic surgery (including robot-assisted laparoscopic and robot-assisted open surgery), accounting for 56.2% of the total cases. 149 patients (8.6%) underwent laparoscopic surgery (including laparoscopic-assisted open surgery), and 504 patients (29.1%) underwent open surgery.

The average total cost for all cases was ￥122,879.5 RMB (￥47,758.1), with an average surgical cost of ￥48,179.0 (￥26,756.3) and an average hospital stay of 19 (10) days.

The average length of stay, total costs, and surgical fees for different surgical types are shown in Table 2. Robotic surgery patients had shorter hospital stays, but higher total costs and surgical fees compared to other surgical methods.

Table 2. Average Length of Stay, Total Costs, and Surgical Fees for Patients with Different Surgical Types

Surgical Types	Length of Stay	Total Costs (￥)	Surgical Fees (￥)
Laparoscopic surgery	18.77	85652.28803	28323.69037
Laparoscopic surgery+open surgery	23.89	118478.8566	42804.68293
Robotic surgery	16.73	119525.9664	57934.14641
Robotic surgery+Laparoscopic surgery	15.46	114223.1089	45608.77628
Robotic surgery+open surgery	22.82	160547.6558	65960.4476
Open surgery	21.24	88360.36195	17172.21624
Total	18.61	106898.0196	41912.90313

A total of 74 out-of-hospital cases have been cleaned. The results show the following costs: Patient time costs: ￥5,777.2 RMB (￥3,870.2); Family member time costs:

￥7,010.0 (￥4,486.0); Average transportation cost: ￥4,389.5 (￥5,917.9); Patient accommodation cost: ￥2,675.1 (￥4,097.3); Family member accommodation or accompanying costs: ￥2,394.6 RMB (￥3,977.5); Patient nutrition costs: ￥585.5 (￥1,514.1); The average non-medical and indirect costs for patients with different surgical types are shown in Table 3. Robotic surgery patients had lower transportation costs and patient time costs compared to other surgical methods.

Table 3 . Average Non-Medical and Indirect Costs for Patients with Different Surgical Types

Surgical Types	Transportation cost (￥)	Family member accommodation or accompanying costs (￥)	Patient accommodation cost (￥)	Patient nutrition costs (￥)	Patient time costs (￥)	Family member time costs (￥)
Laparoscopic surgery	5125	1500	225	625	7420.8	8505.6
Robotic surgery	3783	2446	2720	1187	5523	7193
open surgery	6306	2795	2930	38	5731	6373
Total	4847	2488	2566	707	5777	7010

B.Research Data Acquisition Progress

Direct Non-Medical and Indirect Costs through Surveys.—A total of 74 valid questionnaires have been collected. The survey collection process is as follows:

(i) The ward nurses at Chinese People's Liberation Army General Hospital are responsible for gathering the survey data.

(ii) Data collection started for pancreatic cancer patients discharged from September 2nd onwards. Patients who underwent pancreatic resection surgery, including those who had robotic, laparoscopic, or open surgery, are included in the study, with 80 cases from each group.

(iii) Both patients and their family members are eligible to fill out the questionnaires.

(iv) To ensure accuracy and minimize disruption to patients and clinical operations, the questions are simple, easy to understand, and kept to a minimum in number, after communication with the clinicians.

Medical Costs through Hospital Data Extraction.—A total of 12,166 cases of patients who underwent robotic, laparoscopic, or open pancreatic resection surgeries from January 1, 2014, to September 12, 2024, were identified based on surgical procedure keywords in the hospital system. After further filtering by diagnosis, 4,713 cases were identified as pancreatic malignancies. Future data collection will continue by screening for patients diagnosed with malignant tumors in the ampulla of Vater, who are confirmed to have pancreatic malignancies. Currently, data extraction has been completed for 1,730 cases of pancreatic malignant tumors.

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Macro influencing factors and spatial spil-over effect of high-tech health technology distribution in China: evidence of surgical robot

BY TING CHEN LU AO AND YUHANG PAN . JAY PAN*

Against the backdrop of rapid economic development, the demand for healthcare services among the population is increasingly growing, exhibiting a trend toward higher levels and greater diversity. High-tech medical and healthcare technologies are crucial measures for promoting high-quality development in the medical field. However, the diffusion and distribution of healthcare technologies in China face numerous information gray areas, posing challenges to equity. This study focuses on surgical robots to explore the reasons behind the differentiated diffusion of high-tech healthcare technologies in China, providing empirical support for the literature and relevant regulatory policies. Based on analyses from the first three quarters, this section of the study is divided into two main parts. First, it examines the influencing factors, employing panel regression analysis at the regional level to assess the impact of macro factors (PEST: Political, Economic, Social, and Technological) on healthcare technology diffusion. Second, based on these influencing factors, the study analyzes the spatial spillover effects of technology to explore the temporal and spatial lag of healthcare technology diffusion. The results indicate that political, economic, social, and technological factors all significantly influence the diffusion and distribution of surgical robots in China. A higher proportion of total regional healthcare expenditures, higher education

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* Jay Pan: HEOA Group, West China School of Public Health and West China Fourth Hospital, Sichuan University, No. 17, Section 3, Renmin South Road, Chengdu, China. E-mail: panjie.jay@scu.edu.cn.

levels, higher market competition intensity, and improved overall innovation capacity contribute to the diffusion and advancement of innovative healthcare technologies. The diffusion of healthcare technologies exhibits positive spatial spillover effects, and market competition also has an interregional spillover effect on healthcare technology diffusion. The diffusion of high-tech healthcare technologies reflects regional and socioeconomic inequalities. Greater regional emphasis on healthcare, healthy market competition in the medical sector, and a region's own innovation environment and capacity all facilitate the spread of innovative healthcare technologies. Moreover, technological advancements in one region can drive progress in surrounding areas, creating a virtuous cycle.

I. Backgroud

From the 1978 Alma-Ata Declaration proposing "primary health care for all by 2000" to the 2015 UN Special Summit proposing "achieving sustainable development goals by 2030" (including guaranteeing "health for all throughout the life span"), the international community has always advocated a core concept that everyone should have equal access to health(United Nations 2015). Since 1978, when China began its market-oriented economic reforms, the country has made many substantive efforts to achieve universal health coverage, especially universal coverage of basic medical insurance and basic public health services(Tang et al. 2008). Health equity has been mentioned many times by the government, pointing out that the broad masses of people should enjoy equitable, accessible, systematic and continuous health services such as prevention, treatment, rehabilitation and health promotion(the Xinhua News Agency 2024).

Therefore, the concept of "health equity" has received more and more attention. Although published studies have reported inequalities in health status(Zhang and Kanbur 2005; Tang et al. 2008), health care services (National Health Commission 2021; Tang et al. 2008), health insurance (Yang et al. 2021), and health resources (including professional health personnel) (Liu et al. 2016) at the national level in China, only a few studies have focused on the equity of the distribution of high-tech medical equipment. In particular, a study of two common high-tech medical equipment in China (computed tomography (CT) and magnetic resonance imaging (MRI)) found that before 2004, the distribution of these two technologies in China was relatively equitable across the country, while the results after 2006 showed that the equity of high-tech equipment was low and its distribution was significantly correlated with regional socioeconomic level (He, Yu, and Chen 2013). Although China has made great breakthroughs in universal coverage of basic health services, the concentration of high-quality resources is still inevitable. In 2024, the CPC Central Committee issued the Decision on Further Deepening Reform and Promoting Chinese Modernization, emphasizing that deepening the reform of the medical and health system should "promote the expansion and sinking of high-quality medical resources and regional balanced layout" (the Central Committee of the Communist Party of China 2024).

As one of the leading cutting-edge medical technologies, surgical robots have experienced rapid diffusion in China since the adoptionof the first Da Vinci surgical robot in 2006, driven by their technological advantages and social benefits. However, compared to international trends, China remains in the early stages of surgical robot technology diffusion. Studies show that since the emergence of surgical robots in 2000, over 50% of hospitals in the U.S. had adopted them for surgeries by 2015. In contrast, after 15 years since its first adoption in China, by 2021, only 224 medical institutions were equipped with surgical robots, accounting for just 0.61% of hospitals nationwide, indicating significant market potential for this technology in China. Additionally, robotic-assisted surgeries can help alleviate the shortage of high-quality medical professionals in underdeveloped regions. Surgical experience is often a key determinant of a surgeon’s performance(Sosa et al., n.d.). The clinical advantages of surgical robots include easing the physical strain on surgeons (such as prolonged standing and hand fatigue), providing a high-resolution 3D view, eliminating hand tremors, and enabling precise execution of a surgeon’s intended actions (Lanfranco et al. 2004). These factors contribute to shortening the learning curve for surgeons, allowing younger and less experienced doctors to reach a higher level of proficiency more quickly (Frieberg et al. 2024), As a result, surgical robots facilitate the downward penetration of high-quality medical services, promoting equitable access to advanced healthcare resources.

Regional factors, such as economic and demographic conditions, are considered major drivers of the unequal distribution of technological diffusion (Varabyova et al. 2017). This study further examines the determinants of technological resource allocation using surgical robots as a case study. Research from developed countries, including the U.S. (Mohanty et al. 2022), Switzerland (Stalder et al. 2024), Australia, and New Zealand

(Royal Australasian College of Surgeons 2021), has explored the inequitable distribution of surgical robots and its causes. These studies have found that regional economic levels, geographic location, openness to innovation, and market competition significantly influence healthcare technology adoption disparities (Varabyova et al. 2017). However, China lacks empirical research on this topic. The Chinese healthcare market operates under a dual system of centralized planning and market coordination, a model that is gaining recognition among international scholars (Cutler 2024). The role of market forces and other factors within this mechanism remains to be further explored.

Moreover, prior analysis in this research series has revealed spatial clustering in healthcare technology allocation, suggesting that the adoption of healthcare technology in one region not only benefits the local population but also fosters technological advancement in surrounding areas through spatial spillover effects. Additionally, the technological status of a region may be influenced by its previous levels of development. To quantify these spillover effects, this study innovatively employs a spatial panel model to analyze the diffusion of healthcare technology. Ultimately, this research provides empirical evidence to support the expansion of high-tech medical resources in China and the promotion of high-quality healthcare development. It also offers empirical foundations for the literature and relevant regulatory policies.

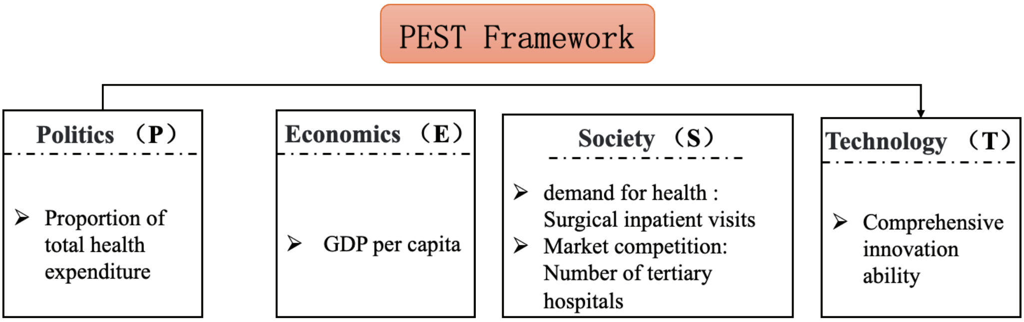
II. Data and Methods

For data, this study examined the adoption of surgical robots in China, utilizing data from a leading robotic service provider that holds an absolute market share advantage, accounting for over 90% of surgical robot usage in mainland China. 1) Regional Data, including permanent population, primarily come from the China Statistical Yearbook (2008–2022) and provincial statistical yearbooks. Population data at the county level were aggregated from WorldPop’s 1×1 km population grid dataset. Following the regional classification of the National Bureau of Statistics of China, the study categorizes 31 provinces, autonomous regions, and municipalities (excluding Taiwan, Hong Kong, and Macau) into three regions: Eastern region (11 provinces/municipalities): Beijing, Tianjin, Hebei, Shandong, Liaoning, Shanghai, Jiangsu, Zhejiang, Fujian, Guangdong, and Hainan. Central region (8 provinces): Shanxi, Jilin, Heilongjiang, Anhui, Jiangxi, Henan, Hubei, and Hunan. Western region (12 provinces/autonomous regions/municipalities): Inner Mongolia, Guangxi, Chongqing, Sichuan, Guizhou, Yunnan, Tibet, Shaanxi, Gansu, Qinghai, Ningxia, and Xinjiang. 2) Healthcare-Related Data, were collected from:China Health Statistical Yearbook (2008–2012), China Health and Family

Planning Statistical Yearbook (2013–2017) and China Health and Wellness Statistical Yearbook (2018–2022);3) Regional Innovation and Education Data, including Regional innovation capability: Sourced from the China Regional Innovation Capability Evaluation Report (2007–2021), Regional education levels: Obtained from the China Education Statistical Yearbook. 4) Hospital Location and Distance Calculation, to determine hospital locations and calculate inter-institutional distances for constructing a distance-weighted matrix, we extracted hospital names and verified their addresses through official hospital websites, and then retrieved the corresponding geographic latitude and longitude data via the Amap (Gaode) API.

Prior sequential studies indicated significant regional disparities in the allocation of healthcare technology resources, showing inequality at both per capita and per unit area scales. These disparities appear to correlate with factors such as regional economic development levels, policy resources, healthcare demand, and market size. To further investigate the macroeconomic factors influencing the adoption of healthcare technologies, this study employed a panel regression model covering 2007–2022. Given that surgical robots represented a high-tech medical innovation, their primary consumer market in China remains tertiary hospitals—as of 2022, all hospitals that had adopted surgical robots were tertiary hospitals. Consequently, in selecting market-related factors, this study primarily considered the healthcare market within high-level medical institutions.

In the selection of relevant factors, we mainly used the PEST macro-environment analysis framework to construct relevant analysis based on the literature review and previous studies. The PEST theoretical framework consists of four parts: political, economic, social and technological. This model framework is one of the most commonly used macro-environment analysis tools, which is used to analyze various macro forces that affect the development of industries or enterprises (Aguilar 1967). Therefore, the independent variables of this study mainly include political factors: the total health expenditure invested by the government, economic factors: the economic level of the region, with per capita GDP as the proxy variable (the consumer price index CPI is used to adjust the impact of inflation); social and cultural factors: regional demand factors, this study mainly focuses on the health needs of the region, with the number of surgical hospitalizations as the proxy variable, and the education level of residents, reflecting the possible demand level of residents for regional innovative technologies (QIongqi Xiao and Kangwang, n.d.); In addition, indicators of the degree of competition in the medical market are also included. The number of suppliers in the market is often used to measure the intensity of market competition. Generally speaking, the more suppliers there are, the more intense the market competition is. In some of the initial studies on hospital competition, the number of hospitals was often used to measure the intensity of hospital market competition (Gaynor and Town 2011). Since then, some scholars have further proposed other indicators based on the number of hospitals, including the number of tertiary hospitals and the number of new hospitals (Lu et al. 2021). This study used the "number of tertiary hospitals" in the region as a proxy variable for market size and market competition. The technical factor sourced from the comprehensive scientific and technological innovation level index in the "China Regional Scientific and Technological Innovation Capability Evaluation Report".



PEST macro environment analysis framework

Methodologically. First, considering the data situation of the study, the influencing factor analysis mainly used mixed cross-sectional linear regression model (OLS), fixed effect linear regression model (FE), and fixed effect negative binomial regression model (NB-FE) for modeling and estimation. Since the data of health technology resources are panel data (balanced panel), this study mainly used panel data analysis strategy for relevant exploratory analysis. Panel data has different analysis strategies and methods from cross-sectional data, mainly including fixed effect and random effect regression models, which have some advantages: First, by introducing individual fixed or random effects, the problem of omitted variables can be effectively solved. When there are unobservable individual differences, the fixed effect model can capture these differences, thereby reducing the error terms in the model and improving the accuracy of the estimate; at the same time, since panel data contains both cross-sectional and time series information, this enables the fixed effect model to provide more variation in individual dynamic behavior, and the model can analyze the changes and dynamic processes of individuals at different time points. The basic model is as follows:

$$(1)\quad Y_{jt} = \boldsymbol{X}'\boldsymbol{\beta} + \alpha_j + \varepsilon_{jt}, \text{ in which}$$

$$\boldsymbol{X}' = (1, x_1, x_2, x_3, \dots, x_n), \quad \boldsymbol{\beta} = \begin{pmatrix} \beta_0 \\ \beta_1 \\ \beta_2 \\ \beta_3 \\ \dots \\ \beta_n \end{pmatrix}$$

Where j represents the province and t represents time. Y represents the proxy variable for health technology resources. X represents the independent variable matrix, including regional economic and demographic factors, health demand factors and market size factors, as well as the addition of year dummy variables to control unobservable time fixed effects. α represents the individual fixed effects that are related to the province and city and constant on the time scale but unobservable, and ε is the disturbance term. The vector β represents the coefficient of the independent variable matrix X. Where β_0 is the intercept term, and $\beta_{1,}\beta_{2,\dots,}\beta_n$ are the coefficients of the independent variables (including time fixed effects). At the same time, considering that the proxy variable of health technology resources, that is, the number of surgical robots, can only take non-negative integers, the dependent variable that cannot meet the requirements of ordinary linear regression obeys or approximately obeys the normal distribution, which will cause serious heteroscedasticity problems and biased estimates. Therefore, this study uses the Poisson regression model (when the mean and variance are equal) or the negative binomial regression model (Wooldridge 2010; Coxe, West, and Aiken 2009) (overdiscrete data, that is, the variance is much larger than expected) as a better choice when the value of the dependent variable can only be a non-negative integer.

Secondly, this study further explored the spatial spillover effect of health technology diffusion after controlling relevant macro-influencing factors, that is, the adoption of health technology by various provinces and cities may affect each other, especially the surrounding provinces and cities. The spatial panel model is mainly used for correlation analysis. Commonly used spatial panel models include spatial autoregression model (SAR) and spatial durbin model (SDM). SAR is a dependent variable with a spatial lag term added to Formula 1; if a spatial lag independent variable is added to SAR, it is SDM.

The general form of the spatial panel model is as follows:

$$(2)\ Y_{jt} = \boldsymbol{X}'\beta + \gamma \boldsymbol{w}_j' y_t + \boldsymbol{h}_j' \boldsymbol{X}' \lambda + \alpha_j + \varepsilon_{jt}$$

$$\text{In which,}\ \varepsilon_{jt} = \rho \boldsymbol{w}_j' \varepsilon_t + \epsilon_{jt}$$

$$\boldsymbol{X}' = (1, x_1, x_2, x_3, \dots, x_n),\ \beta = \begin{pmatrix} \beta_0 \\ \beta_1 \\ \beta_2 \\ \beta_3 \\ \dots \\ \beta_n \end{pmatrix},\ \lambda = \begin{pmatrix} \lambda_0 \\ \lambda_1 \\ \lambda_2 \\ \lambda_3 \\ \dots \\ \lambda_n \end{pmatrix}$$

Among them, j represents province, t represents time, and Y represents health technology resources. X represents the independent variable matrix. γ represents the coefficient of the spatially lagged explained variable, β represents the coefficient of the independent variable matrix X, and λ represents the coefficient of the spatially lagged explanatory variable. α represents the individual fixed effect related to the hospital that is constant but unobservable on the time scale, represents the random disturbance term, and w and h are spatial weight matrices. The spatial correlation of the disturbance term is related to whether the spatial error model (SEM) is used. If $\rho w_j'\varepsilon_t$ is 0, it indicates that SEM is not needed. At this time, when $h_j'X'\lambda$ is 0 and $\gamma w_j'y_t$ is not 0, Formula 2 is a spatial autoregressive model (SAR); when $\gamma w_j'y_t$ and $h_j'X'\lambda$are both not 0, Formula 2 is a spatial Durbin model (SDM). If $\rho w_j'\varepsilon_t$ is also not 0, the spatial Durbin error model (SDEM) is used. At the same time, LeSage et al. proposed a Bayesian method for selecting a suitable model, which can calculate the posterior probability of each spatial panel model to screen the best regression model (LeSage and Parent 2007).

The standard addresses of medical institutions were collected from the official websites of each institution, and the longitude and latitude coordinates were converted using the AutoNavi open platform. The data analysis and drawing software for this study was R 4.2.3.

III. Results

According to the PEST theoretical framework, the independent variables of this part of the study mainly include political factors: the total health expenditure invested by the government, economic factors: the economic level of the region, with per capita GDP as the proxy variable (using the consumer price index CPI to adjust the impact of inflation); social and cultural factors: regional demand factors, this study mainly focuses on the health needs of the region, with the number of surgical hospitalizations as the proxy variable, and the education level of residents, reflecting the possible demand level of residents for regional innovative technologies; at the same time, indicators of the degree of competition in the medical market are also added. The number of suppliers in the market is often used to measure the intensity of market competition. Generally speaking, the more suppliers there are, the more intense the market competition is. At the same time, the "number of tertiary hospitals" in the region is used as a proxy variable for market size and market competition for analysis. The technical factors come from the comprehensive science and technology innovation level index in the "China Regional Science and Technology Innovation Capability Evaluation Report". The descriptive statistics of each variable are shown in Table 1, where the level of higher education = the number of students in colleges and universities in the region/the total population of the region*10,000 people, that is, the number of colleges and universities, undergraduates and postgraduates per 10,000 residents.

Table 1—Descriptive Statistics of Variables

Variables	n	Mean	SD	Median	IRQ_1	IRQ_3
Number of surgical robots	465	1.91	3.86	0.00	0.00	2.00
Surgical robot usage	465	601.10	1310.42	0.00	0.00	527.00
Proportion of total health expenditure	465	6.39	1.91	6.12	4.96	12.97
GDP per capita (ten thousand Yuan)	465	4.96	2.91	4.33	2.94	6.32
HIGHER education level	465	233.44	103.21	225.47	182.10	280.47
Number of tertiary hospitals	465	64.34	46.11	53.00	35.00	85.00
Surgical inpatient visits (10,000)	465	89.92	67.36	73.57	41.38	119.62
Comprehensive innovation ability	465	28.91	10.59	26.30	21.22	31.28

Notes: HIGHER education level = Number of students in colleges and universities in the region /the total population of the region * 10 000, that is, the number of colleges and universities and graduate students per 10 000 residents; Proportion of total health expenditure = proportion of total health expenditure in regional GDP

Firstly, this study conducted a Hausman test on the random effects linear regression model (RE) and the fixed effects linear regression model (FE). The results showed that =17.80, $p<0.01$, indicating that the individual effects that are constant on the time scale are related to the independent variables. Therefore, this study used the fixed effects model for panel data analysis. Furthermore, since the proxy variable of medical technology configuration is the number of surgical robots, only positive integer count data can be taken. Further, the overdispersion parameter κ was tested for hypothesis. The mean of the dependent variable was 1.91, and the variance was 14.87, which was much larger than the mean (14.87>1.91). The test found that the overdispersion parameter was 1.331, $p<0.001$, indicating that the distribution was overdiscrete and needed to be analyzed using a negative binomial regression model. At the same time, after the collinearity variance inflation factor (VIF) test, the variance inflation factors of all selected independent variables were less than 4.5 (VIF<4.5), indicating that there was no serious collinearity problem in the regression.

Figure 1 shows the estimated coefficients of macro factors in each dimension and their 95% confidence intervals. Among them, the estimated results of the mixed cross-sectional linear regression model (OLS), the fixed effect linear regression model (FE), and the fixed effect negative binomial regression model (NB-FE) are shown from top to bottom. Taking the fixed effect negative binomial regression model (NB-FE) as the final model, it can be seen that the political factor: the proportion of total health expenditure in total GDP has a significant positive impact on the configuration of health technology. When the proportion of total health expenditure increases by 10%, the configuration of surgical robots increases by an average of 9.8%, that is, the more the government and society pay attention to the health field and the more they invest, the greater the possibility of high configuration of health technology. In terms of economic factors, after controlling other factors and the fixed effects of region and year, the per capita GDP level has no significant effect on the promotion of health technology diffusion. In the general linear regression and fixed effect models, the higher the level of higher education in the region, the smaller the diffusion of health technology, but in the negative binomial regression of the fixed effect model, the level of higher education is significantly positively correlated with the diffusion of health technology, suggesting that the higher the level of education in the region, the more likely it is to introduce high-tech advanced health technologies. The number of tertiary hospitals represents the scale and degree of competition in the medical and health market. The results show that the greater the competition in the medical and health market, the higher the probability of introducing and configuring high-tech health technologies. In addition, after controlling for individual and time variables in the region, the comprehensive innovation capacity of the region and the diffusion of health technology show a significant positive correlation. If the comprehensive innovation capacity of the region increases by 10%, the allocation of health technology resources can increase by 14.8%.

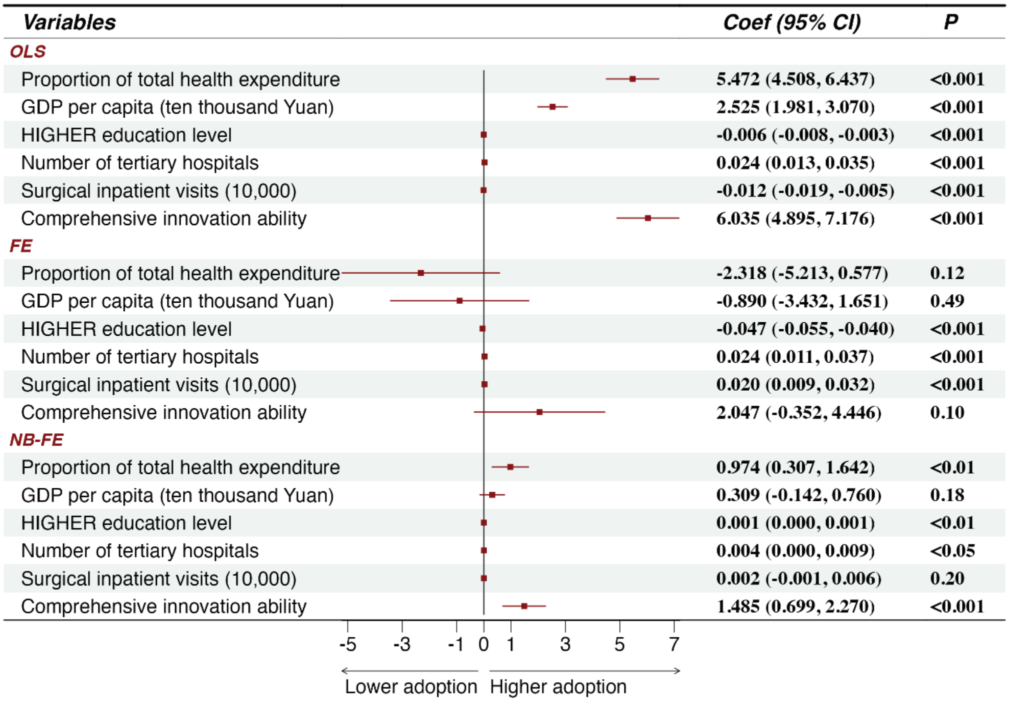


Figure 1. Analysis of Influencing Factors of Health Technology Introduction

Notes: (1) The vertical axis shows the estimation results of mixed cross-sectional logistic regression (OLS), fixed effect linear regression (FE) and fixed effect negative binomial regression (NB-FE) from bottom to top; (2) For the dependent variable regression model, the average marginal effect is shown; (3) Because robust standard errors could not be used for NB-RE and NB-FE, common standard errors were used to calculate the 95% confidence intervals of the estimated coefficients, while robust standard errors were used for other models. (3) HIGHER education level = Number of students in colleges and universities in the region /the total population of the region * 10 000, that is, the number of colleges and universities and graduate students per 10 000 residents; Proportion of total health expenditure = proportion of total health expenditure in regional GDP.

Furthermore, this study used the dynamic spatial panel model to explore the potential impact of spatiotemporal effects. Considering that the spatial panel regression model cannot be directly combined with the limited dependent variable regression model, this section transformed the proxy variables of medical technology configuration and conducted spatial panel regression analysis based on the log-linear regression model. Firstly, the Bayesian method was used to select a more appropriate spatial dynamic panel model (LeSage and Parent 2007; James P. LeSage 2014). Since there is no relevant research and experience to suggest a priori probability for the diffusion of surgical robots, and considering that the dependent variable is count data, we used the prior construction based on the Beta distribution to add a spatiotemporal lag term (dynamic) to select the model, and the Bayesian posterior probability of the model was used to select the best spatial model. As shown in Table 2, the marginal posterior probability (Log-marginal posterior) and model probability (Model probability) of the SDEM model were both the largest. Therefore, we used the dynamic spatial Durbin error model (Dynamic SDEM) as the final model for analysis.

Table 2—Model Selecttion

Model	SAR	SDM	SEM	SDEM
Log-marginal posterior	-1433.22	-1432.52	-1435.65	-1432.24
Model probability	0.1735	0.3496	0.0151	0.4617

Notes: Log-marginal posterior represents the likelihood of the log-transformed marginal posterior. Model probability represents the relative probability of selecting a model.

Table 3 shows the estimated results of the spatial spillover effect of health technology diffusion. Among them, column (1) is a fixed effect model without considering spatial effects, and (2) and (3) show the static Durbin fixed effect model and the dynamic Durbin fixed effect model respectively. The results show that the diffusion of health technology has a positive spatial spillover effect, that is, the adoption of health technology in one region will have a positive impact on the adoptionof health technology in surrounding areas. At the same time, the adoption of regional health technology is not only affected by the current number of health technology introduced in other surrounding areas, but also by the cumulative effect of the adoptionof health technology in the past in itself and neighboring regions. Moreover, this spatial and temporal correlation will make the progress and diffusion of health technology present complex and rich dynamic changes in both spatial and temporal dimensions. At the same time, when this positive effect is transmitted between regions, it also produces a positive feedback effect on the region, thus forming a dynamic cyclical interactive process. Among other macro-influencing factors, it is worth noting that the number of tertiary hospitals has always shown a positive correlation with the adoptionof health technology after considering the temporal and spatial changes of health technology, suggesting that it is a proxy variable for “medical market competition” and emphasizes the importance of market competition in the process of health technology diffusion.

TABLE 3—SPATIAL SPILLOVER EFFECT ESTIMATION

Variables	(1) Fixed Effect Model	(2) SEM	(3) SDEM
Surgical Robot$_{t-1}$			1.18***
			(0.03)
Surgical Robot$_{t-1}$*W			0.22*
			(0.10)
Proportion of total health	-2.32	-1.71	-0.13
expenditure	(1.48)	(1.38)	(0.80)
GDP per capita	-0.89	-1.77	-1.57*
(ten thousand Yuan)	(1.30)	(1.26)	(0.77)
HIGHER education Level	-0.05***	-0.04***	0.00
	(0.00)	(0.00)	(0.00)
Number of tertiary hospitals	0.02***	0.02***	0.01***
	(0.01)	(0.01)	(0.00)
Surgical inpatient visits	0.02***	0.00	-0.00
(10,000)	(0.01)	(0.01)	(0.00)
Comprehensive innovation	2.05	1.76	0.57
ability	(1.22)	(1.13)	(0.66)
Proportion of total health		7.02*	-2.12
expenditure*W		(0.01)	(1.64)
GDP per capita *W		7.88**	-0.44
		(2.47)	(1.50)
HIGHER education		0.01	0.00
Level *W		(0.01)	(0.01)
Number of tertiary		-0.08***	0.01
hospitals *W		(0.02)	(0.01)
Surgical inpatient visits *W		0.07***	-0.01
		(0.01)	(0.01)

Comprehensive innovation ability*W		-10.17*** （2.35）	1.73 （1.42）
Region effects	Yes	Yes	Yes
Time effects	Yes	Yes	Yes

Notes :(1) Surgical Robot$_{t-1}$ represents the lag term of health technology numbers, and Surgical Robot$_{t-1}$*W represents the interaction term between the lag of health technology numbers and the spatial matrix; (2) Proportion of total health expenditure = proportion of total health expenditure in regional GDP; The unit of number of surgical inpatients was 10,000 people. HIGHER education level = number of institutions of higher learning in the region/total population of the region * 10 000 people

IV. Discussion and summary

This study combined relevant classic literature and theories to propose a macro-influencing factor framework and spatial spillover effect hypothesis to promote the diffusion of regional innovative health technologies. Based on data from 31 provinces in China from 2007 to 2021, the frontier negative binomial panel fixed effect model and dynamic spatial Durbin model are used to empirically analyze the impact mechanism and spatial spillover effect of regional health technology progress, taking surgical robots as representatives of high-tech medical technology. The study found that political, economic, social and technological factors will have a significant impact on the diffusion distribution of surgical robots in China, and the diffusion of health technology has a spatial spillover effect. The proportion of regional total health expenses, the level of higher education, the degree of market competition and the improvement of comprehensive innovation capabilities are all conducive to the diffusion of innovative health technologies; at the same time, the diffusion of health technologies has a positive spatial spillover effect, and regional technological progress will have a driving effect on technological progress in surrounding areas. The impact of market competition on the diffusion of health technologies also has a spillover effect between regions.

According to the literature review, the current research on the influencing factors of the diffusion of innovative high-tech health technologies often only considers one aspect (such as medical market competition, regional innovation capabilities, etc.), or stays at the qualitative and theoretical level. There is still a lack of empirical evidence to comprehensively explore the analysis of the influencing factors of the diffusion of health technologies. At the same time, there is no discussion from the perspective of spatial correlation and spatial spillover effects. The results of this study confirm the relevant theoretical assumptions in the field from an empirical level, and further innovatively propose the spatial spillover effect of the diffusion of health technologies, providing a new theoretical perspective and evidence basis for the formulation of relevant theoretical research policies on health technology progress and diffusion.

The diffusion of high-tech health technologies has regional and socioeconomic inequalities. The degree of regional attention to health care, the healthy competition in the medical market, and the region's own innovation environment and innovation capabilities are all conducive to the diffusion of innovative health technologies. Regional technological progress will also drive technological progress in surrounding areas, creating a virtuous circle. This study uses the proportion of regional total health expenditure to regional total GDP as a proxy variable for the region's emphasis on the medical and health sector and policy inclinations. It includes government health expenditure, social health expenditure, personal health expenditure, and expenditure and investment in related fields such as health research. Compared with the "total per capita health expenditure" used in previous studies, this variable takes into account the level of development of the region itself (Varabyova et al. 2017)interest, and authority: medical-individualistic, fiscal-managerial, and strategic-institutional decisional systems. This review aims to examine the determinants of the adoption of medical technologies based on the corresponding decision-making system. We included quantitative and qualitative studies that analyzed factors facilitating or inhibiting the adoption of medical technologies. In total, 65 studies published between 1974 and 2014 met our inclusion criteria. These studies contained 688 occurrences of variables that were used to examine the adoption decisions, and we subsequently condensed these variables to 62 determinants in four main categories: organizational, individual, environmental, and innovation-related. The determinants and their empirical association with adoption were grouped and analyzed by the three decision-making systems. Although we did not identify substantial differences across the decision-making systems in terms of the direction of the determinants' influence on adoption, a clear pattern emerged in terms of the categories of determinants that were targeted in different decision-making systems.","container-title":"Health Policy (Amsterdam, Netherlands and can better reflect the region's emphasis on the health sector. The empirical results verify the correlation between investment in the health sector and technological progress. On the one hand, the level of higher education can reflect the region's demand for innovative technologies. Similarly, in research, it is often used as a reflection of the degree of openness of a region, that is, the open environment of regional innovation and innovation adoption. The results show that the improvement of regional higher education levels is positively correlated with regional technological progress. Similarly, the comprehensive innovation capacity of a region itself represents the region's inclination, investment and acceptance of innovative technologies (QIongqi Xiao and Kangwang, n.d.). Technological innovation and technology introduction complement each other. Technology introduction provides the basis and resources for innovation. On this basis, innovative technology can achieve technological catch-up and sustainable technological progress and a benign technological development model.

The impact of competition in the medical and health market on medical and health services has always been controversial. On the one hand, like other markets, competition is the most important manifestation of the market mechanism. Effective competition can promote lower prices, higher quality and efficiency of products and services in the market, thereby improving consumer welfare. On the other hand, due to the particularity of the medical and health market (such as information asymmetry, etc.), the activities and effects of competition in the medical market may lead to the failure of the market mechanism, resulting in unnecessary welfare losses (Mankiw 2020). Due to the particularity of the medical field, in most cases, patients cannot directly obtain relevant information about the quality and service capabilities of hospitals, nor can they make up for the information gap through repeated consumption as in general commodity markets. Therefore, in the medical and health market, patients (consumers of technology) tend to rely on the advanced medical technology owned by the hospital as the basis for evaluating the hospital's service capabilities (Aggarwal et al. 2017; 2018; Lu et al. 2021), which leads to the tendency of medical institutions to introduce high-tech health technologies to demonstrate their medical service capabilities and levels and attract more patients. The empirical analysis of this study shows that increased competition in the medical market is related to the diffusion of innovative technologies, and this effect has a spatial spillover effect (not only affecting the market itself, but also promoting technological progress in surrounding markets). However, the cost of introducing advanced medical technology is high. Under unreasonable economic incentives and payment methods based on project fees, hospitals may take unreasonable actions, such as inducing demand, transferring configuration costs to patients, and increasing patients' medical expenses (Pan, Qin, and Hsieh 2016; Aggarwal et al. 2017). Therefore, considering this aspect, the government and academia need to strengthen further research and construction of the management of supervision and evaluation systems. At the same time, the empirical analysis of this study is based on the provincial level, and the division of the medical and health market is relatively rough. There is an urgent need for more detailed research at the statistical level to verify the real-world status and laws of the diffusion of health technology.

High-tech and advanced medical equipment are the main manifestations of medical technology and the main focus of hospital technology investment. At present, compared with developed countries such as Europe, the United States, and Australia, China's technical configuration and relative usage of surgical robots are still insufficient. The market space for surgical robots is relatively large. Before the large-scale popularization of technology, it is necessary to strengthen the planning and attention to the fairness of technology distribution, especially as regional differences are becoming more and more severe. The abnormal points of clustered distribution indicate objective technological gaps. At the same time, technology pioneers can provide empirical experience of technology for later adopters, and provide an evidence basis for the "appropriate" diffusion of technology that is tailored to local conditions.

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Review of Health Technology Assessment for Surgical Robots

By Tiantian Zhang*

This article comprehensively explores the health technology assessment of surgical robots. Firstly, it introduces the definition of health technology assessment and emphasizes its importance in providing scientific information and decision-making basis for decision-makers at all levels. Next, it discusses the value dimensions of health technology using two flowers of value - the new and the old, with a specific focus on the value dimensions of medical devices including surgical robots. Furthermore, the article analyzes the evaluation path of surgical robots within the IDEAL framework, including three stages of evaluation recommendations from the perspectives of device developers, clinical doctors, patients, and the healthcare system. Additionally, the article provides detailed discussions on specific considerations during the HTA process of surgical robots and gives corresponding suggestions. These considerations include evidence inclusion and exclusion, patient and surgeon perspectives, learning curve effect, cost allocation, analysis methods, time horizons, organizational impact, and incremental innovation. The aim is to overcome assessment challenges and improve the accuracy and reliability of evaluation results. Finally, the article emphasizes the complexity and importance of HTA for surgical robots, and looks forward to innovative and future development of evaluation methods, with the goal of providing stronger support for medical decision-making, promoting the rational application of surgical robots, and improving the quality of medical services.

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*Zhang: Southern Institute of Pharmacoeconomics and Health Technology Evaluation, Jinan University.

I. Health technology assessment

A. Definition

In 2020, the World Health Organization, in collaboration with several international organizations, provided the following definition and explanation for Health Technology Assessment (HTA): HTA evaluates various interventions for disease prevention, diagnosis, treatment, health promotion, and rehabilitation, including pharmaceuticals, biologics, medical devices, health materials, medical protocols, operational procedures, organizational management systems, logistics support systems, etc. It provides scientific information and decision-making basis for healthcare technology choices to decision-makers at all levels, including governments, health insurance companies, patients, and healthcare professionals (O'Rourke B et al., 2020).

B. Value dimensions

Health technology assessment requires the evaluation of the value of health technologies, which have different dimensions of value, typically including clinical effectiveness, safety, cost and economic impact, ethics, social, cultural, and legal issues, among others.

In 2017, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) introduced the "flower of value" for health technologies, which covers thirteen value elements and is widely recognized (Lakdawalla et al, 2018). As time has progressed, in 2023, the organization "No Patient Left Behind" in the United States released the "flower of value" for generalized cost-effectiveness analysis (GCEA), which originates from costs and effects and includes fifteen broader value elements in four categories. This is greatly beneficial for future health technology assessments (Shafrin et al., 2024). The mapping of the petals (i.e., value elements) of the old and new flowers is shown in Table 1.

Table 1 Mapping GCEA value petals to ISPOR value flower

Category	GCEA	ISPOR
Uncertainty	Outcome Uncertainty	Value of Hope
		Reduction in Uncertainty
	Disease Risk Reduction	Insurance Value
	Value of Knowing	-
Dynamics	Dynamic Net Health Costs	Net Costs
	Dynamic Prevalence	-
	Societal Discount Rate	-
	Option Value	Real Option Value
	Scientific Spillover	Scientific Spillovers
Beneficiary	Patient-Centered Health Improvements	Quality-Adjusted Life Years (QALYs) gained
		Severity of Disease
	Equity	Equity
	Family and Caregiver Spillover	Productivity
Additional Value Elements	Community Spillover	Fear of Contagion
	Productivity	Productivity
	Adherence	Adherence Improving Factors
	Direct Non-Medical Costs	Net Costs

C. Value dimensions of medical devices

Medical devices are also a type of healthcare technology, but there are inherent differences between medical devices and drugs due to various factors such as different methods of operation/administration, the process of generating clinical evidence, implementation and requirements of research, as well as different product lifecycles. These differences further result in variations in the value dimensions of medical devices and healthcare technologies such as drugs. The value dimensions of medical devices are listed in Table 2.

Table 2 Value dimensions of medical devices

Dimension	Content
Clinical Value	Meet unmet clinical needs (increase or improve new functions); Enhance safety (reduce risks); Improve clinical efficiency; Enhance diagnostic and therapeutic effects; Increase accessibility of technology; Improve key technical parameters of the product.
Economic Value	Reduce other direct/indirect medical expenses; Save costs for equipment and materials; Reduce operation and maintenance costs for diagnosis and treatment; Lower treatment costs; Decrease medical service prices; Provide cost-effectiveness analysis with better results; Budget impact.
Innovation	Domestic first imitation, with partial contributions to research and development; Independent research and development. Prior to the release of the achievements, discover simultaneous development of similar products abroad, with a registration certificate time difference not exceeding one year in an uncontrollable country; Globally leading, with breakthrough research and development results.
Technical Characteristics	Maturity of medical devices, personnel requirements, equipment requirements, technical maintenance requirements, operational skills, etc.
Societal Suitability	Social and environmental changes that may arise from using the medical device, including social, ethical, and legal changes; Whether or not it exacerbates social health inequality.

II. The IDEAL framework for surgical robots

Surgical robot is one of medical devices, it combines the latest achievements in precision mechanics, computer science, biomedical engineering, and other disciplines. It is a revolutionary advancement in the field of modern medicine. Since the late 20th century, surgical robots have undergone a process of development, from initial exploration to widespread application. Initially, surgical robot systems were primarily used to assist doctors in performing precise surgery. With technological advancements, surgical robots are now capable of performing complex surgical tasks such as minimally invasive surgery and remote surgery. The application of surgical robots can improve the accuracy and safety of surgeries, reduce human errors in operations, minimize patient trauma and postoperative complications, improve patient prognosis, enhance quality of life, shorten recovery time, and provide new surgical tools and methods for surgeons.

The “IDEAL Framework and Recommendations” introduced by the IDEAL Council aims to establish a scientific and rigorous evaluation pathway for new surgical procedures, invasive medical devices, and other complex therapeutic interventions. It recommends key elements for implementing research methods and reporting standards based on the developmental stage of the intervention. Currently, IDEAL has become an internationally recognized paradigm for surgical clinical research methodology. In 2024, the IDEAL Council published the IDEAL Framework for Surgical Robots, which provides evaluation recommendations for the development, comparative research, and clinical monitoring of surgical robots from the perspectives of device developers, clinical doctors, patients, and the broader healthcare system (Marcus et al., 2024). The three stages are as follows: IDEAL stages 0, 1, and 2a, which involve early clinical research on the safety and feasibility of the new concept of surgical robots; IDEAL stages 2b and 3, which involve larger-scale studies on the effectiveness of robotic interventions and comparing them with the current best practices; and IDEAL stage 4, which focuses on long-term monitoring of performance in real-world settings when robots are widely adopted. Specific recommendations for each stage and perspective are listed in Table 3.

Table 3 Recommendations for each stage and perspective of the IDEAL framework for surgical robots.

IDEAL stage	stakeholders	Recommendations
0(pre-IDEAL) 1(ideal) 2a(development)	developers	1、Standardize the publication (in peer-reviewed journals) of technical and clinical data. 2、Transparently document changes to devices, indications, patients and AI models. 3、AI-integrated robot evaluation should initially examine AI facets separately, followed by in silico and simulator-based assessment of the integrated robot (IDEAL stage 0). First-in-human studies (IDEAL stage 1) and beyond should assess the integrated robot in a clinical context, using clinical outcomes, guided by reporting guidelines (for example, DECIDE-AI). Evaluate robotic autonomy based on level and risk.
	clinicians	Define, analyze and iterate clinician–device integration accounting for stakeholder perspectives, clinician behavior and cognitive workload. For autonomous systems, evaluate the reliability of handover mechanisms and reasons for human takeover.

IDEAL stage	stakeholders	Recommendations
	patients	Ensure transparent consent processes regarding theoretical risks, evidence, system failure mitigation, autonomy level, surgical team experience and potential conflicts of interest.
	healthcare systems	Perform early and iterative economic modeling, using exploratory analyses to guide cost-effective development and prevent future research wastage. Consider the impact of surgical robots on different healthcare ecosystems, using life cycle assessments, reverse engineering and frugal design concepts where possible to improve accessibility and sustainability.
2b(exploration) 3（evaluation)	developers	Risks and benefits of surgical robots must be evaluated through prospective data collection using a suitable study design, mutually agreed dataset, appropriate analysis techniques and assessment of study-specific confounders. Robot reevaluation for alternative indications should be based on risk, autonomy level and available evidence.
	clinicians	Validated tools and qualitative research should be used to explore human factors. The real-world learning curve for surgical robots must be investigated. Metrics should be collected from direct supervision of both real-world and simulated use cases. Establish institutional clinical governance policies with consistent specifications on surgeon training, audit and ethics.
	patients	Explore robotic surgery acceptability through assessing patient perspectives, understanding, and consent. Maintain transparency with participants regarding existing evidence, development stage, conflicts of interest, surgical experience, complications and alternative treatment.
	healthcare systems	Economic impact analysis of healthcare costs associated with robotic intervention should be measured in comparative studies, including clinically and system-relevant outcomes over a sufficient length of follow-up. Include stakeholders from low-resource settings in modeling capacity, benefit and risks of robot use, compared against available alternatives. Life cycle assessments of surgical robots should be compared to the current gold-standard treatment.

IDEAL stage	stakeholders	Recommendations
4 (long-term monitoring)	developers	Long-term monitoring should be led by RWD tailored to provide high-quality, transparent and valid data. Evaluation of surgical robots must be customized to accommodate for their dynamic nature, specifically with regards to AI-enabled systems and to detect device creep.
	clinicians	Standardized training programs, informed by comparative stage findings, should be used and recognized by accrediting bodies. Surgeon revalidation and credentialing should be performed to ensure robotic surgery skills are maintained to a high standard. All adverse events should undergo human and systems factors analysis with dedicated experts.
	patients	Registries and long-term monitoring studies should be independently procured, and readily available in formats that are understandable to patients. Patient-reported outcome measures should predominate in long-term monitoring studies to ensure outcomes remain patient centered.
	healthcare systems	Cost-effectiveness analysis of surgical robots should be performed, informed by real-world, data-driven, decision-analytic modeling. International forums should assess and mitigate global health inequities introduced by surgical robotics. Sustainability and environmental impact assessment are imperative in long-term evaluation, guided by regular consultation with expert stakeholders.

It is worth noting that the IDEAL Framework for surgical robots emphasizes the requirement for economic evaluation at each stage. During the conceptualization and development stage, early economic modeling and exploratory analysis are needed to guide economically viable development. In the exploration and evaluation stage, the economic impact of the robot intervention on healthcare costs needs to be measured in comparative studies, including clinical and system-related outcomes over a sufficiently long follow-up period. Finally, in the long-term monitoring stage, cost-effectiveness analysis of surgical robots should be conducted, and decision analysis models driven by real-world data should provide information. Therefore, special attention should be paid to the challenges in economic evaluation of surgical robots and appropriate measures should be taken to address them. For example, Simianu et al. (2020) constructed a decision analysis model to conduct cost-effectiveness evaluation of open surgery, laparoscopic surgery, and robot-assisted surgery for colon resection from the perspectives of the society and the healthcare system. The results showed that laparoscopic and robot-assisted colon resection surgeries were more cost-effective than open surgery (Simianu et al., 2020).

III. Considerations and suggestions for HTA of surgical robots

Surgical robots, as a type of health technology, also require assessment. However, as surgical robots are a technology distinct from other health technologies, there are some issues in conducting health technology assessment for them. Therefore, special attention and careful consideration are required. Below, we will list some important considerations and provide corresponding recommendations.

A. Inclusion and exclusion of evidence

Clinical research on surgical robots is usually limited, resulting in a scarcity of literature. Additionally, due to the lack of appropriate controls, randomization, and blinding, the quality and reliability of evidence generated in clinical research may be compromised. Moreover, these studies are often small in scale, which may limit their generalizability when evaluating surgical interventions. Therefore, it is worth considering the inclusion of other types of evidence such as case reports, cohort studies, case-control studies, and real-world studies, while paying attention to the quality of the evidence.

B. Perspectives of patients and surgeons

Focusing only on rigid clinical outcomes in the health technology assessment of surgical robots may overlook factors that provide information for health policy decision-making, such as patient benefits, or ergonomic benefits for surgeons. Therefore, it is necessary to consider results that reflect the perspectives of patients and surgeons, such as patient preferences and satisfaction, as well as the comfort and efficiency of surgeons during the surgical process.

C. Learning curve effects

As the number of practice sessions increases, the performance of surgeons in using surgical robots gradually improves, leading to different health outcomes, which further affects the associated costs and introduces uncertainty in the assessment. Therefore, when conducting health technology assessment for surgical robots, the differences in clinical abilities among surgeons should be considered, and the learning curve effect should be corrected whenever possible (Erskine et al., 2023). This requires using data that is suitable for the surgical volume and the experience with surgical robots in the specific study setting when selecting evidence of clinical effectiveness. It is also necessary to analyze the changes in clinical evidence related to surgical robots over time to observe if their performance is stable. Sensitivity analysis should be used to explore the impact of corresponding changes in performance. For quantifying the learning curve, a three-stage method proposed by the European network for Health Technology Assessment can be referred to.

D. Allocation of costs

Surgical robots themselves do not directly perform the intervention but need to be incorporated into one or more surgeries. However, in some health technology assessments, allocating the entire capital cost of the surgical robot system to a single surgery volume may result in biased outcomes. A more reasonable approach is to allocate the cost across all surgeries performed with the robot, calculating the cost based on the actual number of surgeries performed by the surgical robot. Only in this way can the current utilization of surgical robots in covering various patient surgeries by hospitals or healthcare systems be more comprehensively reflected.

E. Analysis methods

Currently, many economic evaluations of surgical robots only consider the costs compared to traditional surgical methods, making the assessment results not comprehensive and having limited reference value. The value-based healthcare (VBHC) approach should be used, which reflects the pursuit of the best clinical outcomes with the same or lower costs, maximizing the value obtained from healthcare services rather than simply comparing costs.

F. Appropriate time horizons

When evaluating the surgical outcomes of surgical robots, it is necessary to consider long-term impacts and set a reasonable time horizon. This includes the long-term effects on patient quality of life and economic costs, as well as the potential long-term effects on the well-being of surgeons. These impacts may not immediately manifest and require long-term tracking and research to fully assess. For example, certain clinical outcomes (such as recurrence) may only become apparent years after the surgery. Once these clinical outcomes occur, they can have a long-lasting impact on patient quality of life and economic costs, potentially even lasting a lifetime.

G. Organizational impact

Surgical robots can bring additional benefits to the entire organization of a hospital, which are often not considered in health technology assessments. These benefits include improved hospital operational efficiency, facilitation of data analysis, and remote surgery capabilities. Therefore, the value of the entire robotic ecosystem should be taken into account. Additionally, the implementation of surgical robots often requires substantial organizational investments and adaptations, such as new infrastructure and the creation and supervision of multidisciplinary teams. If the cost of implementing surgical robots is borne by healthcare providers, the analysis should include the costs of setting up the robotic-assisted surgical platform and the expenses incurred for optimizing the use of the robot platform, such as training. The impact of these costs should be evaluated in sensitivity analyses (Lai et al., 2024). Furthermore, the proportion of open and laparoscopic surgeries that may be replaced by robot-assisted surgeries should also be considered.

H. Incremental innovation

Surgical robot devices and their technologies are constantly evolving, especially with the integration of artificial intelligence. The introduction of new models or products can influence clinical outcomes and costs, rendering health technology assessments quickly outdated or rendering the research process itself ineffective (Marcus et al., 2024). To address these issues, innovative and iterative evaluation strategies such as implementation trials can be employed (Wolfenden et al., 2021). Additionally, the Bayesian approach, which integrates prior knowledge and continuously incorporates new information, is more applicable in these cases (Ming et al., 2021).

IV. Conclusion

Surgical robots, as an advanced technology in the field of medical devices, require the health technology assessment (HTA) to ensure their reasonable application in medical practice and the effective allocation of resources. However, the complexity of surgical robot HTA requires us to consider various factors comprehensively in the evaluation process. It is necessary to pay special attention to the quality and applicability of evidence, fully consider the perspectives of patients and doctors, as well as factors such as learning curve, cost allocation, analysis methods, time horizons, organizational impact, and incremental innovation. These considerations aim to overcome the challenges in the evaluation process and improve the accuracy and reliability of evaluation results. In summary, HTA for surgical robots is a complex and systematic process that requires the integration of multidisciplinary knowledge and methods, as well as continuous exploration and innovative assessment strategies. In the future, with the continuous advancement of technology and the evolution of the medical environment, HTA methods for surgical robots should keep pace with the times to better serve medical decision-making, promote the development of surgical robot technology, and ultimately achieve the goal of improving medical quality and patient well-being.

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机器人在中国医院的采用：分析计划

梁钧霆　潘聿航*

摘　要　我们实证研究了医疗机器人首次使用对中国医院科室绩效的影响。采用结合了双向固定效应（TWFE）和事件研究（Event-Study）方法的稳健分析框架，分析了从2013年1月到2022年12月的每日科室数据。我们的重点是量化首次使用这种先进的手术技术后，对科室总收入的影响。

一、引言

由于中国前所未有的经济发展和日益增长的需求，中国已成为手术机器人增长最快的国家之一。这篇文章将研究中国医院，特别是科室里达芬奇手术系统（达芬奇外科手术系统）的技术采用情况。截至 2022 年，达芬奇手术机器人的母公司--直观复星 Intuitive Fosun--被认为是最大的机器人辅助手术（Robotic Assisted Surgery）技术培训供应商，并获得 FDA 等认证。全球有超过 70 个国家近 7000 台达芬奇系统执行了超过 1000 万次微创机器人手术程序（薛瑞华、刘荣，2021）

达芬奇外科系统于 2006 年首次在中国引入，当时中国人民解放军总医院采用了该系统。从 2006 年至 2023 年，共有 284 家中国医院实施了达芬奇 RAS 系统。这一技术随后被 2000 多名外科医生用于多种手术，这些外科医生共进行了 180 多种手术，其中泌尿科的手术量最高，约为 15 万次。

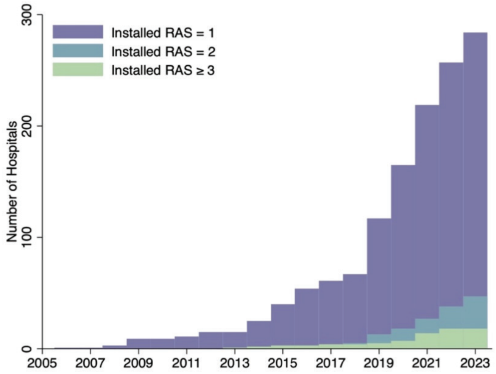

图 1. 中国拥有达芬奇手术系统的医院数量

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* 梁钧霆：北京大学全球健康发展研究院（E-mail：kwanting@stu.pku.edu.cn）；潘聿航（通信作者）：北京大学全球健康发展研究院（E-mail:yhpan@pku.edu.cn）。我们感谢达芬奇提供的市场数据。文中所有的错误均由作者承担。

中国医院现有的达芬奇手术系统包括：DaVinci SP、DaVinci S、DaVinci Si和DaVinci Xi。我们主要关注达芬奇手术系统在不同类别和不同科室中进行的第一台手术。图1展示了达芬奇手术系统在中国医院的普及情况。可以观察到两个显著的增长期。第一个发生在2014年，当时配备达芬奇系统的医院数量几乎翻倍。第二次增长发生在2019年，配备达芬奇手术系统的医院数量从69家增加到119家。

图2描绘了安装达芬奇手术系统和其在各个外科部门首次使用之间的时间间隔。数据表明，普通外科和泌尿外科部门从系统安装到运行的时间间隔较短，可能是由于这些领域手术对达芬奇手术系统高需求和直接适用性。达芬奇手术系统可用于广泛的手续程序。在泌尿外科，它可以执行前列腺、肾脏和膀胱癌的微创手术。在普通外科领域，该系统可以在复杂的消化系统里进行胃癌和直肠癌的微创手术切除。胸外科则利用达芬奇的先进能力处理肺癌和食管癌等疾病。在妇科，达芬奇系统可以用于子宫切除，宫颈癌，卵巢癌等妇科癌症。在图2的分类基础上，我们的分析扩展到医院部门级别，包括小儿外科、胃结直肠外科、肝胆胰外科和甲状腺外科。如图3所示，只有甲状腺外科在达芬奇系统安装与其首次操作之间有显著间隔，这表明某些专业对达芬奇辅助手术机器人的应用仍处于开发阶段。

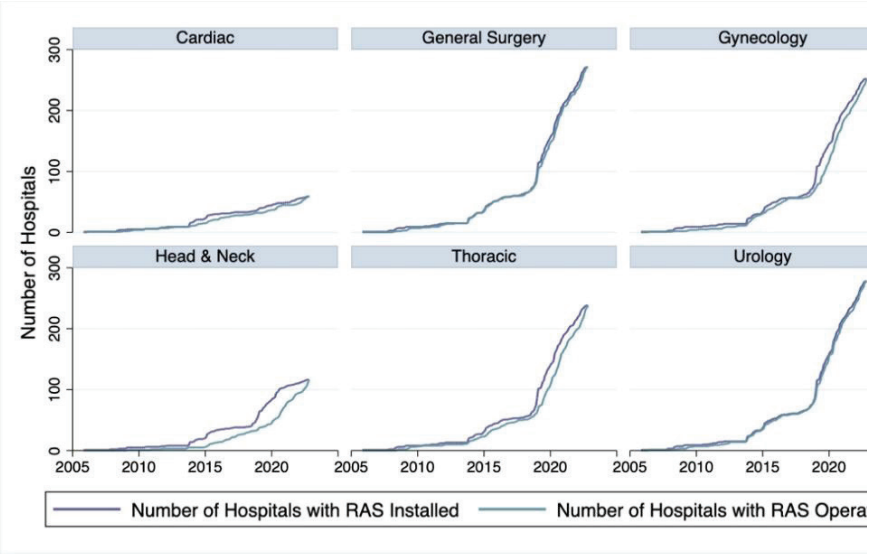

图 2. 医院各类别安装与首次使用时间间隔

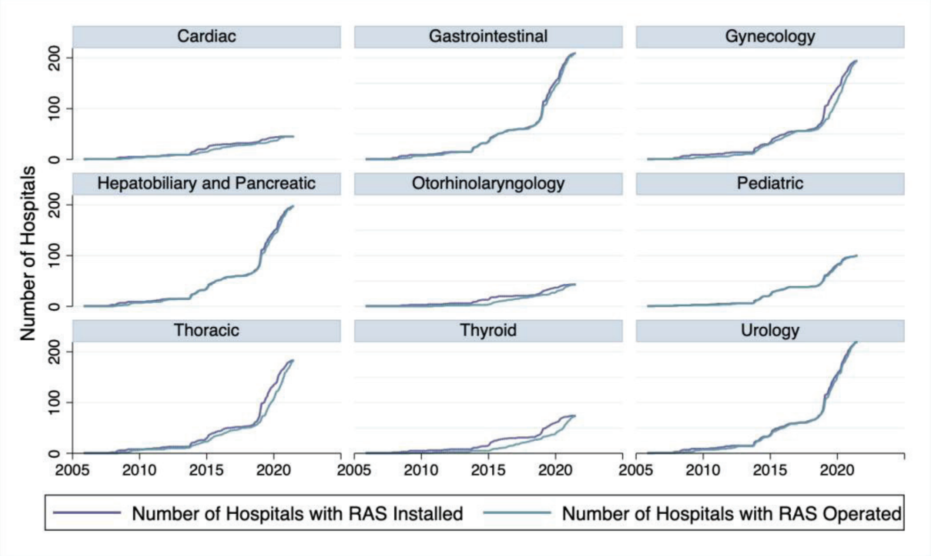

图 3. 医院各科室安装与首次使用时间间隔

二、数据

每个观测值代表单个病人整个住院期间的信息，病人级别的数据按科室级别每日汇总。数据包括病人特征、消费、住院时间和入院及出院日期。我们假设病人在住院期间每天花费相同，根据他们的总消费除以住院时间计算每日收入。

病人特征信息包含性别和年龄段。性别包括 1 代表男性，2 代表女性，3 代表未知。分配了六个年龄组：0-15 岁，16-30 岁，31-45 岁，46-60 岁，61-75 岁，以及 76 岁以上。计算了三种类型的病人特征：第一，为目前在医院的所有病人累计；第二，为刚入院的病人；第三，为刚出院的病人。

三、描述统计

表 1 中的摘要统计展示了控制组和处理组的医院层级指标概览，以月和周为单位进行分段统计。关键指标包括平均住院时间、患者数量、科室死亡率、总收入、自费收入和护理收入，覆盖了从 2013 年 1 月到 2022 年 12 月的时间段。

处理组的平均入院患者数量显著高于控制组，这表明配备达芬奇系统的医院可能处理更复杂或高级的病例。通常配备达芬奇系统的医院是具备更大接待能力的三甲医院。处理组的平均患者数量是控制组的 2.5 倍左右，其科室层级的总收入、自费收入和护理收入几乎是控制组的 4.7 倍。

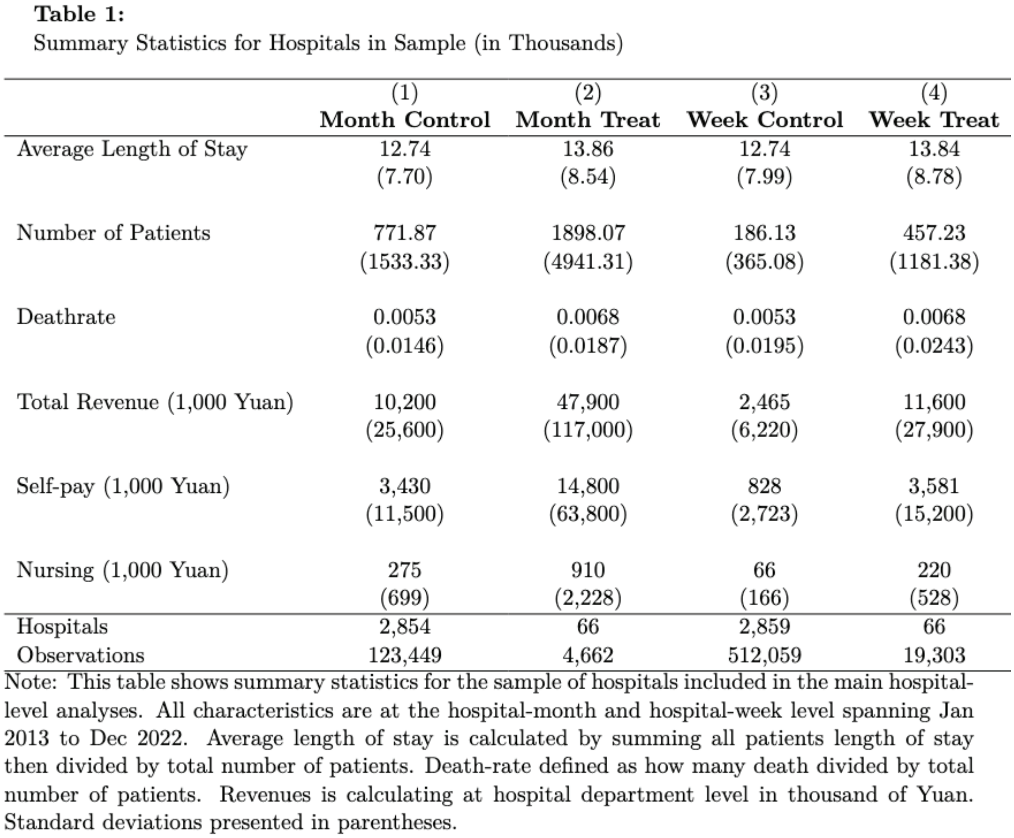

Table 1:
Summary Statistics for Hospitals in Sample (in Thousands)

	(1) **Month Control**	(2) **Month Treat**	(3) **Week Control**	(4) **Week Treat**
Average Length of Stay	12.74	13.86	12.74	13.84
	(7.70)	(8.54)	(7.99)	(8.78)
Number of Patients	771.87	1898.07	186.13	457.23
	(1533.33)	(4941.31)	(365.08)	(1181.38)
Deathrate	0.0053	0.0068	0.0053	0.0068
	(0.0146)	(0.0187)	(0.0195)	(0.0243)
Total Revenue (1,000 Yuan)	10,200	47,900	2,465	11,600
	(25,600)	(117,000)	(6,220)	(27,900)
Self-pay (1,000 Yuan)	3,430	14,800	828	3,581
	(11,500)	(63,800)	(2,723)	(15,200)
Nursing (1,000 Yuan)	275	910	66	220
	(699)	(2,228)	(166)	(528)
Hospitals	2,854	66	2,859	66
Observations	123,449	4,662	512,059	19,303

Note: This table shows summary statistics for the sample of hospitals included in the main hospital-level analyses. All characteristics are at the hospital-month and hospital-week level spanning Jan 2013 to Dec 2022. Average length of stay is calculated by summing all patients length of stay then divided by total number of patients. Death-rate defined as how many death divided by total number of patients. Revenues is calculating at hospital department level in thousand of Yuan. Standard deviations presented in parentheses.

四、实证模型

本节介绍了用于评估达芬奇手术系统首次使用对各科室结果影响的实证分析。我们采用双重差分 (DID) 方法，利用包含医院和科室的面板数据来估计这一先进手术技术的因果效应。以下总结了实证模型、识别策略和主要发现。DID 识别策略利用了达芬奇系统在医院和科室首次使用时间上的差异。通过比较安装或首次使用前后的科室结果，并与尚未采用该系统的科室进行对比，DID 方法旨在将达芬奇系统的因果效应与其他混杂因素区分开来。

我们使用广义双重差分 (TWFE) 方法来估计达芬奇手术系统的影响，其中结果变量通过一组表示安装前后时间的事件时间虚拟变量回归。模型定义如下（He 和 Wang，2017）：

$$Y_{i,j,t} = \alpha + FirstProc_{i,j,t} + \rho_{i,j} + \vartheta_t + \epsilon_{i,j,t}$$

其中，$Y_{i,j,t}$ 表示医院 i、科室 j 在年份 t 的结果变量，$FirstProc_{i,j,t}$是一个

虚拟变量,如果医院 i、科室 j 在年份 t 已开始使用达芬奇机器人系统,则取值为 1,否则为 0。ϑ_t *and* $\rho_{i,j}$ 分别表示时间和医院科室的固定效应。标准误差在医院和科室层级进行聚类。

五、平行趋势检验与事件研究

在我们的实证策略中，回归模型中包括了医院科室和时间的固定效应，实质上采用了广义的双重差分模型。为了确保在达芬奇手术系统使用之前，处理组和对照组的结果趋势是平行的，我们实施了事件研究方法。参照 Jacobson 等人 (1993) 和 He 和 Wang (2017) 的方法，我们估计了以下方程：

$$Y_{ijt} = \alpha_{ij} + \delta_t + \beta_k \times \sum_{k=24}^{k\leq -12,\, k\neq 1} D_{ijt}^{k} + \epsilon_{ijt}$$

我们的结果变量 Y_{ijt} 是医院 i 科室 j 在时间 t 的不同收入的组合。Y_{ijt} 包括每日收入、入院总收入、出院总收入、自费服务收入、手术护理其他病理诊断、实验室诊断、影像学诊断、临床诊断、非手术治疗、手术治疗、康复收入。

虚拟变量 D_{ijt} 共同代表达芬奇首次使用事件，将医院 i 科室 j 首次安装达芬奇机器人系统的年份定义为 s_i 。我们定义 $D_{ijt}^{-12} = 1 \text{ if } t - s_i \leq -12$ 否则为 0。在基准模型中，我们控制了是医院 i 科室 j α_{ij} 和时间 δ_t. 的固定效应。标准误差在医院层面上聚类；在未来的稳健性检查中，我们将在更小的类别层次上聚类。

六、基准结果

表2展示了每月的双重差分(DID)回归分析结果。这些结果表明，达芬奇系统的首次使用与平均住院时间的显著减少相关。首次使用程序的系数（标记为"first_proc"）为-1.181，在 5% 水平上显著。这表明在首次使用达芬奇系统后，患者的住院时间平均减少约一天，反映出机器人辅助手术程序的效率和效果提升。在平均住院时间的对数形式中，我们发现减少了-0.066%，在 5% 水平上显著。然而，死亡率的变化不具有统计上的显著性，系数接近零，这与外科医生的定性见解一致，即达芬奇系统在死亡率方面对患者风险无显著影响。

在科室收入方面，自费收入显著增加了 1.385，一个可能的解释是因为中国的保险政策不覆盖高端技术手术。除了达芬奇手术外，患者还可以选择由保险覆盖的

约 ¥5,000 的腹腔镜手术。然而，达芬奇手术的费用约为 ¥30,000，需患者自费支付。我们未观察到首次使用达芬奇系统对其他科室结果（例如总收入的系数为 0.099，护理收入的系数为 -0.196）有显著影响。不过，人均护理收入显著减少了 -0.1955（在 1% 水平上显著），这表明患者因住院时间缩短而产生的护理费用较低。

Table 2: Month DID Regression Results

VARIABLES	(1) avgstay	(2) deathrate	(3) patient	(4) lnavgstay	(5) lndeathrate	(6) lnpatient
First_proc	-1.182**	0.001	-74.987	-0.066**	0.001	0.113
	(0.502)	(0.000)	(55.465)	(0.030)	(0.000)	(0.125)
Obs.	126641	126641	126641	126641	126641	126641
Adjusted R-Square	0.524	0.367	0.736	0.587	0.380	0.839

VARIABLES	(7) lnzfy	(8) lnzfje	(9) lnhlf	(10) pplnzfy	(11) pplnzfje	(12) pplnhlf
First_proc	0.099	1.385*	-0.196	-0.016	0.958*	-0.217***
	(0.139)	(0.788)	(0.150)	(0.038)	(0.499)	[0.041)
Obs.	126641	126641	126641	126641	126641	126641
Adjusted R-Square	0.795	0.801	0.779	0.674	0.801	0.749

Note: All dependent variables are transformed using levels and natural logs where specified. Fixed effects at the hospital department and time level are included. Robust standard errors are reported in parentheses. *** p<0.01, ** p<0.05, * p<0.1.

七、事件研究结果

图 4 通过展示科室层面的自费收入点估计值及其 95% 置信区间来可视化动态效果。每个点表示事件前或事件后特定周或月的处理虚拟变量的估计系数。值得注意的是，自费收入在事件后第七个月开始表现出显著的增长趋势，显示出达芬奇系统对患者支出具有显著的积极影响。在第二张图中，护理收入在事件后第六个月开始呈现下降趋势，并在第十二个月及之后达到 5% 的显著性水平。

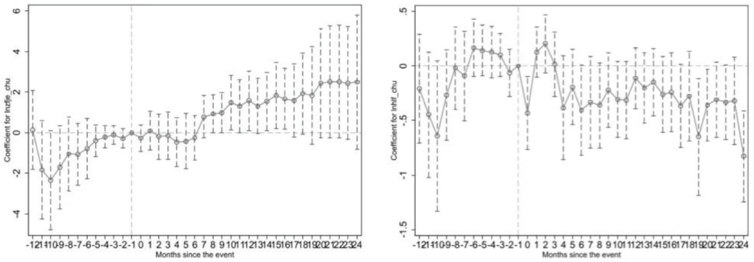

表 4. 自费收入以及护理收入的事件研究

八、稳健性检验

为了确保结果的稳健性，我们进行了额外的事件双重差分 (Event DD) 和分期双重差分 (Stagger DID) 分析，未发现相互冲突的系数。

九、异质性分析

我们进一步进行了针对特定科室的双重差分回归和事件研究分析，重点关注了心脏外科、普通外科、妇科、胸外科和泌尿外科等达芬奇系统使用频率较高的科室。此外，我们筛选了数据，集中于老年患者或极年幼患者较多的科室。最后，我们分别考察了达芬奇系统对男性和女性患者的影响。

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Health Economics Study of Robots and Laparoscopy for Hepatocellular Carcinoma Resection

By Xiao Liang, Haijing Guan, Junhao Zheng, AND Chenyue Yang

机器人与腹腔镜肝切除术治疗肝细胞癌的卫生经济学研究

梁霄 官海静 郑俊浩 杨辰越*

摘　要　背景：相比腹腔镜肝切除术，机器人肝切除术可以降低术后并发症发生率、住院时间，提升患者术后生命质量。然而，机器人肝切除术的费用较高，使用机器人肝切除术治疗肝细胞癌是否具有经济性，目前仍然缺乏中国证据。目的：探索机器人肝切除术相比腹腔镜肝切除术用于肝细胞癌切除术的临床价值与医疗费用。方法：我们回顾性收集了2016年1月至2023年7月浙江大学附属邵逸夫医院单一医疗团队内接受微创肝切除术的肝细胞癌患者的数据，将患者分为研究组即机器人肝切除组与对照组即腹腔镜肝切除组，进行倾向性评分匹配后，比较匹配前后的围术期指标和医疗费用，并以手术难度为协变量进行亚组分析，分析不同手术难度下两种术式围术期预后和医疗费用的差异。结果：共有277例患者被纳入本研究（腹腔镜肝切除组175例，机器人肝切除组102例）。在应用倾向性评分匹配控制混杂因素后，共162例患者（两组各81例）被纳入进一步分析。结果显示，机器人肝切除组相比腹腔镜肝切除组术中出血、术后并发症较少、中转开腹率较低，手术安全性更好。机器人肝切除组具有更高的医疗费用（82885.3元 vs. 58643.8元，$p<0.001$），然而，腹腔镜肝切除组除手术外的其他各项费用显著更高。亚组分析显示，在高难度肝切除术中，两种术式的费用没有显著差异。结论：对于肝细胞癌患者，机器人肝切除比腹腔镜肝切除具有更好的手术安全性和更高的医疗费用，同时，高手术难度患者采用机器人肝切除术更具有经济性。

一、引言

机器人肝切除术（robotic liver resection，RLR）作为一项新技术，相比腹腔镜肝切除术(laparoscopic liver resection，LLR)可能具有更佳的手术安全性，但其手术费用往往更高。因此，使用机器人切除术治疗肝细胞性肝癌(Hepatocellular

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*　梁霄，浙江大学医学院附属邵逸夫医院；官海静，首都医科大学附属北京天坛医院；郑俊浩，浙江大学医学院附属邵逸夫医院；杨辰越，浙江大学医学院附属邵逸夫医院。通信作者：梁霄（E-mail：srrshlx@zju.edu.cn）

carcinoma，HCC）是否具有经济学效应，目前仍然缺乏相关证据。

当今机器人肝切除相关的卫生经济学研究在国内外报道较少。2022年1篇纳入了4篇相关文献的meta分析显示，RLR（20,205.92美元）的成本远远高于LLR（15,789.75美元）。费用是制约RLR开展的重要因素（Ciria等 2022）。然而，随着现代医学的发展，手术不仅是为了治愈，也是为了提高生活质量。2020年Mejia等报道了214例肝切除患者，指出与LLR相比，RLR尽管费用更高，但患者住院时间更短，对于小范围肝切除患者是更好的选择（Mejia等 2020）。然而，2016年我国学者根据机器人和腹腔镜肝左外叶切除手术的39例患者资料指出，对于肝左外叶切除，RLR比LLR手术费用更昂贵，但在疗效和安全上差异无统计学意义（尹注增等 2016）。因此，RLR是否能改善生活质量并具有成本效益仍然是一个争论。

2023年的国际机器人肝切除专家指南指出，相较于LLR，RLR在肝脏相关疾病中具有独特的治疗价值，其成本效用值得未来继续研究（Liu等 2023）。在泌尿外科、大肠外科等学科中，已有研究认为机器人手术具有成本效益，或者指出有利于提高机器人的应用率所需降低的费用（Simianu等 2020；Song等 2022）。

二、研究方法

开展真实世界研究，回顾性收集浙江大学附属邵逸夫医院2016年1月-2023年7月诊断为HCC的住院患者，根据患者的手术方式分为RLR组与LLR组，在描述性分析的基础上，通过倾向性评分匹配控制混杂因素，探索不同治疗方式对于治疗结局和医疗费用的净效益，并进行经济学评价。开展亚组分析，探索研究结果的稳健性。

正态分布的连续变量描述为平均值 ± 标准差，偏态分布的连续性变量描述为中位数（四分位距），分类变量描述为频率和百分比。将年龄、BMI、AFP、INR、ALB、AST、TBIL、Child分级、血管浸润、手术难度、ASA分级作为协变量纳入模型进行拟合，计算倾向性评分，进行最邻近法匹配。PSM采用SPSS 25.0版本进行分析。将患者按照IWATE手术难度分级分为“低难度”“中等难度”“高难度”“专家难度”4个亚组，进行亚组分析。

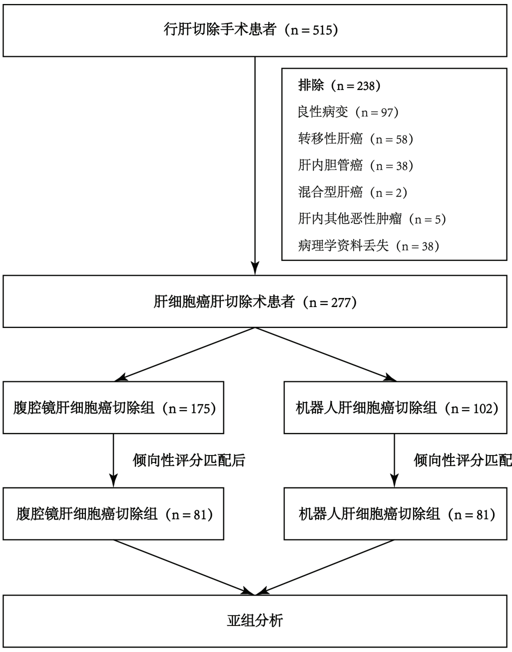

图 1. 纳入、排除标准及流程图

三、结果

经纳入、排除标准筛选后，共有 277 例患者被纳入本研究，根据手术方式分为 LLR 组（175 例）和 RLR 组（102 例）。PSM 后，两组各 81 例进一步进行比较分析。

（一）患者基线指标

在倾向性评分之前，LLR 组的 BMI、AFP、PLT、INR、ALB、AST、肝硬化、Child-Pugh 分级、门脉高压、IWATE 手术难度分级与 RLR 组有显著性差异（均 $p < 0.05$）。余指标均无显著性差异。经过倾向性评分匹配平衡基线指标后，162 例患者（LLR 组与 RLR 组各 81 例）纳入进一步分析，LLR 组与 RLR 组的基线指标均无显著性差异。（附表 1）

（二）患者临床结局指标

在倾向性评分之前，LLR 组的术中出血量（100.0 vs. 50.0 ml，$p < 0.001$）、术中输血率（33 [18.8%] vs. 10 [9.8%]，p=0.045）、术后并发症发生率（35

[20.0%] vs. 7 [6.8%]，p=0.003）、术中转开放率（20 [11.4%] vs. 0 [0.0%]，p=0.001）、术后住院时间（6.0 vs. 5.0 day，p=0.001）、总住院时间（13.0 vs. 9.5 day，p=0.001）显著高于RLR组，其余指标均无显著性差异（均p≥0.05）。经过倾向性评分匹配平衡基线指标后，共162例患者（LLR组与RLR组各81例）被纳入研究，LLR组的术中出血量（100.0 vs. 50.0 ml，p=0.002）、术后并发症发生率（16 [19.8%] vs. 7 [8.6%]，p=0.043）、术后住院时间（6.0 vs. 5.0 day，p=0.005）、总住院时间（12.0 vs. 10.0 day，p＜0.001）显著高于RLR组，其余指标均无显著性差异（均p≥0.05）。（附表2）

（三）患者费用结局指标

在倾向性评分之前，LLR组的住院总费用（57150.9 vs. 81432.5元，p＜0.001）、自付费用（16875.0 vs. 50333.4元，p＜0.001）、手术费用（6916.0 vs. 43424.9元，p＜0.001）显著低于RLR组，然而药物费用（15879.4 vs. 9955.6元，p＜0.001）、检查费用（1260.0 vs. 1160.0元，p=0.010）、护理费用（1164.0 vs. 989.6元，p=0.001）、耗材费用（21113.4 vs. 12094.4，p＜0.001）显著高于RLR组。经过倾向性评分匹配平衡基线指标后，共162例患者（LLR组与RLR组各81例）被纳入研究，LLR组的住院总费用（58643.8 vs. 82885.3元，p＜0.001）、自付费用（15972.7 vs. 50706.2元，p＜0.001）、手术费用（6616.0 vs. 43424.9元，p＜0.001）、其他费用（341.0 vs. 535.0元，p=0.004）显著低于RLR组，药物费用（16517.6 vs. 9975.0元，p＜0.001）、检查费用（1365.0 vs. 1115.0元，p=0.010）、护理费用（1174.0 vs. 988.6元，p=0.001）、耗材费用（21565.4 vs. 12069.4元，p＜0.001）显著高于RLR组。（附表2）

（四）亚组分析结果

以IWATE手术难度分级为协变量进行亚组分析，结果显示，在“低难度”“中等难度”“高难度”3个亚组内，LLR组的住院总费用显著低于RLR组（低难度：46125.7 vs. 76647.9元，p＜0.001；中等难度：52692.8 vs. 76428.8元，p=0.003；高难度：67548.3 vs. 84725.0元，p=0.001），然而，在“专家难度”组内，LLR组与RLR组的住院总费用没有显著性差异（75709.0 vs. 88292.6元，p=0.325）。（图2）

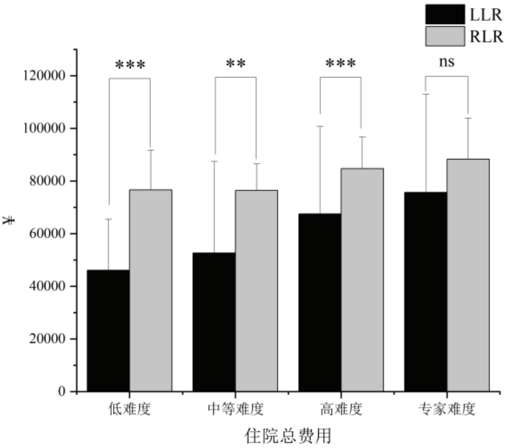

图 2. 住院总费用的手术难度亚组分析

注：

*** 代表 $p < 0.001$

** 代表 $p < 0.005$

ns 代表 $p > 0.05$

将 IWATE 手术难度为“低难度”“中等难度”的患者合为低手术难度组，IWATE 手术难度为“高难度”“专家难度”的患者合为高手术难度组，进行亚组分析。结果显示，在两个手术难度亚组内，LLR 组的术中失血量（低手术难度：100.0(50.0-200.0) vs. 50.0(20.0-150.0)mL，$p=0.013$；高手术难度：200.0(80.0-400.0) vs. 100.0(50.0-137.5)mL，$p=0.024$）、术后住院时间（低手术难度：5.0(4.0-7.0) vs. 4.0(3.0-5.5)days，$p=0.010$；高手术难度：6.5(5.0-9.0) vs. 5.0(4.0-7.0)days，$p=0.046$）、总住院时间（低手术难度：12.0(9.0-16.0) vs. 10.0(7.0-12.0)days，$p=0.005$；高手术难度：13.5(10.0-16.0) vs. 9.5(8.0-12.0)days，$p<0.001$）均显著高于 RLR 组。在两个手术难度亚组内，LLR 组与 RLR 组的其余结局指标均无显著性差异。（附表 3）

四、讨论

近年来肝脏外科发展迅速，与开放手术相比，LLR 手术安全性更好、肿瘤学结局相似、费用相似，在过去十年中已成为肝良恶性病变患者的主要微创手术选择。然而，LLR 视频视图的不稳定、腔镜器械的刚性等限制了其在肿瘤位置隐蔽、手术难

度高的HCC患者人群中的使用。RLR的引入克服了传统LLR的固有局限性，更灵活、精准的操作方式展现出其在复杂、大范围肝癌切除中的优势，并带给患者更好的短期结局，然而，更高昂的手术费用成为制约RLR发展的重要因素。RLR是否具有成本效益仍然是一个争论。

目前国内外对比机器人与腹腔镜肝切除医疗费用的研究报道较少，本研究探索医学机器人相比腹腔镜用于肝细胞癌切除术的临床价值与医疗费用，为肝细胞癌切除患者的外科治疗策略提供了循证医学依据。除此以外，本研究通过IWATE肝切除手术难度分级对肝细胞癌切除患者分组，是国内外首次探究不同手术难度下RLR的成本效益，帮助医生根据不同手术难度的卫生经济学效益，选择更合理的手术方式。真实世界中，各中心机器人手术费用差异较大，因此，本研究患者个体选自同一医疗机构内同一医疗组，以减少组间差异。此外，主刀医师的一致性也减少了术者手术能力对患者预后的影响。为消除基线指标差异对研究结果的影响，本研究利用PSM以减少偏倚。PSM结果显示LLR组与RLR组基线指标均无显著性差异（均$p \geqslant 0.05$）。

为探究RLR相对于LLR是否具有成本效益，我们比较了PSM后两组临床结局指标和费用指标差异。结果显示，两组在手术时间、手术切缘情况、术中输血情况、术中转开腹情况、术后30日因并发症再入院情况方面是相似的，而LLR组的术中出血量、术后并发症发生率、住院时间、术后住院时间显著高于RLR组，证明RLR在手术安全性方面优于LLR。费用方面，LLR组的住院总费用、自付费用显著低于RLR组，进一步佐证了RLR相对于LLR所需的高费用。从住院总费用的构成考虑，我们发现LLR组的手术费用显著低于RLR组，然而，LLR组的药物费用、检查费用、护理费用、耗材费用却显著高于RLR组，提示我们手术费用高是RLR住院总费用显著高于LLR的主要原因，但RLR通过改善患者预后，减少了患者术后用药、进一步检查等需要，反而降低了患者的其他开销。因此，我们认为，尽管RLR总费用高于LLR，但行RLR的患者临床结局更好、手术以外的开销更少，未来通过降低RLR手术费用， RLR将更具有成本效益。

有相关研究表示，机器人手术的高手术费用主要来源于机器人系统本身的使用成本、维护和一次性用品的成本。这与本研究中心的经验相符，机器人手术中机器人的开机费用在手术费用中占据了绝大部分。然而，考虑到机器人系统的持续使用、医疗保险在手术机器人方面的调整以及未来其他机器人生产商引入带来的竞争，预计随着时间的推移，这些成本将逐渐减少，RLR在肝脏外科的使用将进一步增加。

已有大量研究指出，在手术难度高的患者人群中，RLR比LLR更具有优越性。

同时，更高的手术难度往往也要求更高的医疗费用。本研究已发现RLR住院总费用显著高于LLR，然而，是否在不同手术难度的患者间，RLR和LLR所需费用的差异情况存在不同？为探究该问题，本研究根据IWATE手术难度分级定义患者手术难度，进一步以手术难度为协变量进行亚组分析。结果显示，在“低难度”“中等难度”“高难度”3个亚组内，LLR组的住院总费用均显著高于RLR组，然而，在“专家难度”组内，LLR组与RLR组的住院总费用却没有显著性差异（75709.0(64022.6-101275.4) vs. 88292.6(82954.8-98554.0)￥，p=0.325）。因此我们认为，随着手术难度升高，RLR与LLR间的费用差距被缩小。进一步比较各手术难度亚组内RLR与LLR的临床指标，结果显示，无论在低手术难度亚组内，还是在高手术难度亚组内，LLR组的术中失血量、术后住院时间、总住院时间均显著高于RLR组，LLR组与RLR组的其余结局指标均无显著性差异。提示我们，无论手术难度高低，RLR的临床结局均与LLR相当。因此，结合手术难度的提高对两种术式费用差距的减小，本研究认为，对于更高难度的HCC切除手术，RLR相比LLR是更好的选择。

本研究也具有一定的局限性。首先，本研究患者选自单中心单一医疗组，考虑到各中心机器人手术费用存在一定差异，我们的研究结果可能不适用于其他医疗中心。手术医生的技术水平也会对患者手术的成本效益产生影响，这也是本研究选用单一医疗组同一主刀医生进行手术的患者的原因，然而这也同样限制了我们研究结果在其他医疗组的适用性。其次，当前在卫生经济学评价中、特别是在评估新药物、治疗方法、诊断工具或公共卫生干预方案时，常用成本效用分析（cost-effectiveness analysis，CEA）方法。CEA常引入质量调整生命年（quality-adjusted life years，QALY）来评估患者生命质量，最后利用成本和QALY计算提高单位QALY所需的成本，从而评估该检查、干预等的成本效用。然而本研究是一项回顾性研究，没有前瞻性评估患者术后生命质量，而且本次研究所采用的结局指标都是短期结局指标，因此没有计算QALY，无法评估患者的成本效用。最后，本研究没有将购买机器人所需费用这一间接成本纳入分析，主要是考虑到，作为对比的购买腹腔镜的时间更早，不同时期购买力不同，难以直接比较，而且各中心购买机器人的费用也各不相同。

五、结论

本研究证明，对于肝细胞癌患者，RLR比LLR具有更好的手术安全性和相对更高的医疗费用。然而，RLR除手术费用以外的其他费用更低。另外，手术难度的增加提高缩小了两种术式的费用差距，RLR是高手术难度的HCC患者更好的选择。

附表1. PSM前后LLR组与RLR组基线指标

基线指标	PSM前 (n=277)			PSM后 (n=162)		
	LLR (n = 175)	RLR (n = 102)	p值	LLR (n=81)	RLR (n=81)	p值
年龄 (SD), year	58.7±12.2	60.6±11.5	0.056	62.9±11.6	61.4±11.2	0.390
BMI (SD), kg/$^{\mathrm{m}}$2	23.2±2.8	24.1±3.6	**0.021**	23.6±3.0	24.0±3.3	0.406
性别，n(%)			0.309			0.678
女	23(13.1)	18(17.6)		13(16.0)	15(18.5)	
男	152(86.9)	84(82.4)		68(84.0)	66(81.5)	
肿瘤最大径 (IQR), cm	2.6 (1.8-4.3)	3.0 (2.2-4.5)	0.163	2.5 (1.8-4.4)	3.2(2.2-4.7)	0.082
AFP (IQR), ng/mL	17.2 (3.4-277.5)	6.6 (2.5-110.2)	**0.048**	10.2 (3.2-139.8)	6.6 (2.6-110.2)	0.403
PLT (IQR), ×10^9/L	126.0 (89.0-172.0)	143.5 (111.0-191.2)	**0.005**	124.0 (95.5-170.0)	138.0 (108.0-190.0)	0.050
PT (IQR), s	13.8 (13.1-14.6)	13.5 (13.0-14.2)	0.068	13.5 (12.9-14.1)	13.5 (13.1-14.2)	0.437
INR (IQR)	1.0 (1.0-1.2)	1.0(1.0-1.1)	**＜0.001**	1.0 (1.0-1.1)	1.0 (1.0-1.0)	0.307
TBIL(IQR), μmol/L	14.9 (11.1-21.1)	14.8 (11.2-19.1)	0.728	14.2 (9.6-21.3)	15.3 (11.4-18.8)	0.589
ALB (SD), g/L	39.4±4.8	40.9±4..5	**0.013**	40.2±4.4	40.0±3.6	0.794
AST (IQR), U/L	27.0 (18.0-40.0)	30.0 (23.8-38.0)	**0.026**	25.0 (17.0-41.0)	29.0 (23.5-38.0)	0.100
ALT (IQR), U/L	29.0 (22.0-39.0)	27.0 (19.0-42.3)	0.364	29.0 (21.5-39.0)	27.0 (19.0-41.5)	0.559
肿瘤数量，n(%)			0.819			0.658
单发	151(86.3)	87(85.3)		68(84.0)	70(86.4)	
多发	24(13.7)	15(14.7)		13(16.0)	11(13.6)	
肝硬化，n(%)	96(54.8)	41(40.2)	**0.016**	38(46.9)	32(39.5)	0.341
Child-Pugh分级，n(%)			**0.049**			1
A	159(90.9)	99(93.1)		78(96.3)	78(96.3)	
B or C	16(9.1)	3(2.9)		3(3.7)	3(3.7)	
门脉高压，n(%)	11(6.2)	0(0)	**0.028**	5(6.2)	0(0.0)	0.074
既往肝切除，n(%)	22(12.6)	14(13.7)	0.844	12(14.8)	12(14.8)	1
既往开腹手术，n(%)	56(32.0)	35(34.3)	0.693	27(33.3)	31(38.3)	0.512
既往新辅助治疗，n(%)	25(14.2)	10(9.8)	0.279	6(7.4)	9(11.1)	0.416
IWATE肿瘤位置 (IQR)	5.0(3.0-5.0)	5.0(3.0-5.0)	0.949	5.0(3.0-5.0)	5.0(3.0-5.0)	0.576
IWATE肿瘤大小 (IQR)	0.0(0.0-1.0)	1.0(0.0-1.0)	0.179	0.0(0.0-1.0)	1.0(0.0-1.0)	0.140
IWATE手术方式 (IQR)	0.0(0.0-4.0)	3.0(0.0-4.0)	0.195	0.0(0.0-4.0)	0.0(0.0-4.0)	0.946
IWATE靠近脉管 (IQR)	0.0(0.0-0.0)	0.0(0.0-0.0)	0.541	0.0(0.0-0.0)	0.0(0.0-0.0)	0.135

IWATE Child-Pugh (IQR)	0.0(0.0-0.0)	0.0(0.0-0.0)	**0.049**	0.0(0.0-0.0)	0.0(0.0-0.0)	0.988
IWATE手助腹腔镜 (IQR)	0.0(0.0-0.0)	0.0(0.0-0.0)	1	0.0(0.0-0.0)	0.0(0.0-0.0)	1
IWATE总分 (IQR)	6.0(5.0-9.0)	7.0(5.0-9.0)	0.176	6.0(4.0-9.0)	6.0(4.5-9.0)	0.57
IWATE难度分级, n(%)			**0.003**			0.916
低难度	27(15.4)	19(18.6)		16(19.8)	16(19.8)	
中等难度	82(46.9)	28(27.5)		29(35.8)	25(30.9)	
高难度	31(17.7)	35(34.3)		21(25.9)	23(28.4)	
专家难度	35(20.0)	20(19.6)		15(18.5)	17(21.0)	
ASA分级, n(%)			0.206			0.692
Ⅰ级	8(4.6)	1(1.0)		2(2.5)	1(1.2)	
Ⅱ级	155(88.6)	94(92.2)		72(88.9)	75(92.6)	
Ⅲ级	12(6.9)	7(6.9)		7(8.6)	5(6.2)	
Ⅳ~Ⅵ级	0(0.0)	0(0.0)		0(0.0)	0(0.0)	
医疗保险，n(%)			0.074			0.070
城镇职工基本医疗保险	164(93.7)	101(99.0)		74(91.4)	80(98.8)	
其他保险	11(6.3)	1(1.0)		7(8.6)	1(1.2)	
居住地，n(%)			0.803			0.727
本地	47(26.9)	26(25.5)		24(29.6)	22(27.2)	
外地	128(73.1)	76(74.5)		57(70.4)	59(72.8)	

附表2. PSM前后LLR组与RLR组结局指标

结局指标						
	PSM前 (n=277)			PSM后 (n=162)		
	LLR (n = 175)	RLR (n = 102)	p值	LLR (n=81)	RLR (n=81)	p值
手术时间 (IQR)，min	168.0 (125.0-240.0)	165.0(110.0-220.0)	0.263	180.0 (120.0-250.0)	160.0 (107.5-220.0)	0.134
切缘状态，n(%)			0.464			1
R0	172(98.3)	98(96.1)		80(98.8)	79(97.5)	
R1 or R2	3(1.7)	4(3.9)		1(1.2)	2(2.5)	
术中出血量 (IQR)，mL	100.0 (50.0-400.0)	50.0(50.0-112.5)	**<0.001**	100.0 (50.0-275.0)	50.0 (50.0-125.0)	**0.002**
术中输血情况，n(%)	33(18.8)	10(9.8)	**0.045**	12(14.8)	8(9.8)	0.339
术后并发症，n(%)	35(20.0)	7(6.8)	**0.003**	16(19.8)	7(8.6)	**0.043**
ClavienDindo分级, n(%)			**0.006**			0.062
No	140(80.0)	95(93.1)		65(80.2)	74(91.4)	
I or II	25(14.3)	6(5.9)		10(12.3)	6(7.4)	
III or IV or V	10(5.7)	1(1.0)		6(7.4)	1(1.2)	
术中转开腹情况，n(%)	20(11.4)	0(0.0)	**0.001**	5(6.2)	0(0.0)	0.069
住院期间再次手术，n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/
围术期死亡情况，n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/
术后住院时间 (IQR)，day	6.0(4.0-7.0)	5.0(3.8-6.2)	**0.001**	6.0(4.0-7.0)	5.0(3.5-6.0)	**0.005**

术后30天因并发症再入院，n(%)	3(1.7)	1(1.0)	1	2(2.5)	1(1.2)	1
总住院时间（IQR），day	13.0(10.0-16.0)	9.5(7.0-13.0)	**<0.001**	12.0(10.0-16.0)	10.0(8.0-12.0)	**<0.001**
住院总费用（IQR），元	57150.9 (44313.0-76302.3)	81432.5 (74644.9-90934.2)	**<0.001**	58643.8 (45171.2-75899.8)	82885.3 (75617.3-90501.2)	**<0.001**
自付费用（IQR），元	16875.0 (9911.2-23013.9)	50333.4 (46274.6-57632.8)	**<0.001**	15972.7 (8999.7-23056.8)	50706.2 (46796.8-57640.6)	**<0.001**
药物费用（IQR），元	15879.4 (11219.3-23459.2)	9955.6 (7687.4-14007.0)	**<0.001**	16517.6 (11994.0-24028.5)	9975.0 (7861.8-14117.4)	**<0.001**
手术费用（IQR），元	6916.0 (6302.0-7834.3)	43424.9 (42808.6-43897.9)	**<0.001**	6616.0 (6165.0-7481.4)	43424.9 (42754.1-43994.5)	**<0.001**
检查费用（IQR），元	1260.0 (930.0-2153.0)	1160.0 (673.0-1752.8)	**0.010**	1365.0 (1075.0-2340.0)	1115.0 (659.0-1602.0)	**0.001**
护理费用（IQR），元	1164.0 (879.0-1521.0)	989.6 (784.0-1291.3)	**0.004**	1174.0 (832.5-1555.0)	988.6 (779.9-1255.1)	**0.012**
耗材费用（IQR），元	21113.4 (15486.0-31411.4)	12094.4 (10839.8-18034.8)	**<0.001**	21565.4 (15899.2-32842.0)	12069.4 (10898.8-19094.2)	**<0.001**
其他费用（IQR），元	386.0 (182.0-722.0)	486.5 (246.5-851.8)	0.054	341.0(182.0-683.4)	535.0 (276.5-863.0)	**0.004**

附表3. IWATE手术难度亚组的结局指标分析

结局指标						
	低难度 + 中等难度 (n = 86)			高难度 + 专家难度 (n = 76)		
	腹腔镜 (n = 45)	机器人 (n = 41)	p值	腹腔镜 (n=36)	机器人 (n=40)	p值
手术时间（IQR），min	155.0 (100.0-223.8)	120.0 (85.0-180.0)	0.228	195.0(164.0-260.0)	187.5(150.0-240.0)	0.265
切缘状态，n(%)			/			1
R0	45 (100.0)	41 (100.0)		35 (97.2)	38 (95.0)	
R1_or_R2	0(0.0)	0(0.0)		1(2.8)	2(5.0)	
术中出血量（IQR），mL	100.0 (50.0-200.0)	50.0 (20.0-150.0)	**0.013**	200.0 (80.0-400.0)	100.0 (50.0-137.5)	**0.024**
术中输血情况，n(%)	7(15.6)	3(7.3)	0.393	5(13.8)	5(12.5)	1
术后并发症，n(%)	8(17.8)	3(7.3)	0.147	8(22.2)	4(10.0)	0.145
ClavienDindo分级, n(%)			0.063			0.341
No	37 (82.2)	38 (92.7)		28 (78.8)	36 (90.0)	
I_or_II	4(8.9)	3(7.3)		6(16.7)	3(7.5)	
III_or_IV_or_V	4(8.9)	0(0.0)		2(5.6)	1(2.5)	
术中转开腹情况，n(%)	3(6.7)	0(0.0)	0.274	2(5.6)	0(0.0)	0.428
住院期间再次手术，n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/

围术期死亡情况，n(%)	0(0.0)	0(0.0)	/	0(0.0)	0(0.0)	/
术后住院时间（IQR），day	5.0 (4.0-7.0)	4.0 (3.0-5.5)	**0.010**	6.5 (5.0-9.0)	5.0 (4.0-7.0)	**0.046**
术后30天因并发症再入院，n(%)	2(4.4)	1(2.4)	1	0(0.0)	0(0.0)	/
总住院时间（IQR），day	12.0 (9.0-16.0)	10.0 (7.0-12.0)	**0.005**	13.5 (10.0-16.0)	9.5 (8.0-12.0)	**<0.001**

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机器人辅助人工全膝关节置换术与传统膝关节置换术中期随访研究

吕蓓妮 宋洋 周一新*

摘　　要　我国膝关节疾病负担重，其中人工关节置换是治疗终末期膝关节炎最有效的方法。相比于传统的手术方式，机器人辅助膝关节置换有望发送患者预后，但在术后关节功能、疼痛改善、僵直程度、满意度以及整体健康评分方面是否存在优越性尚无定论，更缺少基于中国患者数据的随访研究。本研究纳入单中心202例接受机器人手术的患者，1：1匹配纳入接受传统手术的患者，对患者的中期临床预后和效果指标进行随访。两组患者的基线特征无显著差异。机器人辅助全膝关节置换有1名患者因术后活动过伸进行翻修手术，传统手术组未见翻修，其他假体相关并发症、关节相关住院、手术和门诊就诊、术后关节满意度无显著差异。两组患者的关节功能评分（WOMAC评分）和生活质量评分亦无显著性差异。相比于传统手术，机器人手术组手术时间较长（96.61分钟VS.79.13分钟），但随着机器人手术的开展，机器人组的手术时间在逐渐缩短（p<0.05）。综上，机器人辅助全膝关节置换与传统手术在患者中期临床预后上类似。本研究将继续经济学成本的评估，并构建长期预后模型来进一步明确机器人手术与传统手术相比的卫生经济性。

一、背景

全膝人工关节置换术是治疗终末期膝关节骨性关节炎最为有效的疗法，因其能为患者提供舒适、稳定的人工替代膝关节而被广泛使用(Kim et al. 2020)。自上世纪70年代开始，随着人工关节材料学、人体工程学、生物化学、围手术期管理等技术的提高和理念的创新，全膝关节置换的手术方法、假体类型、预计使用寿命和患者满意度都得到了长足的进步。特别是进入21世纪后，机器人辅助手术使得人工全膝关节置换手术得到了极大的改变。在手术精度方面，与传统手工截骨工具相比较，应用机器人辅助的人工全膝关节手术在定位精度度、精确截骨、个体化置入假体方面有显著进步(邵等 2023；Subramanian等 2019；杨等 2024)。但在术后关节功能、疼痛改善、僵直程度、满意度以及整体健康评分方面，机器人手术与传统手工的人

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*　吕蓓妮，北京大学全球健康发展研究院；宋洋，首都医科大学附属积水潭医院；周一新，首都医科大学附属积水潭医院。通信作者：吕蓓妮（E-mail：blyu@pku.edu.cn）。

工全膝关节置换术的优越性尚无定论。目前关于机器人辅助和传统手工的人工全膝关节置换对比研究往往面临样本量小、随访时间短的局限性，更缺少基于中国患者数据的对比研究。

本研究通过纳入本中心机器人辅助下全膝关节置换手术开展3年来的所有患者，匹配同时期接受传统手术患者，结合回顾性研究与前瞻性随访，致力于明确机器人辅助全膝关节置换与传统手术中期临床疗效的差异。

二、方法

本研究纳入首都医科大学附属北京积水潭医院矫形骨科第一病区2022年2月至2024年3月期间，行机器人辅助下人工全膝关节置换术患者（robotic assistant total knee arthroplasty， r-TKA）。纳入标准为年龄21-80 岁；同意参加本研究；符合接受单侧TKA条件的患者。排除标准为：妊娠期女性患者；膝关节翻修患者；伴有严重的屈曲畸形（＞20°）及严重内外翻畸形（＞20°）的患者；骨质情况无法进行假体安装的患者；手术区域伴有其他金属植入物的患者；存在活动性感染灶的患者；对一种或者多种植入材料过敏的患者；存在髋部疾病，包括髋关节发育异常、严重脱位和髋部骨折等患者；存在麻痹、肌无力等神经肌肉功能不全的患者；合并严重的系统性疾病患者；患有除关节炎以外的慢性疼痛疾病，需长期服用止痛药物的患者。研究根据患者年龄、性别、手术日期（±3个月），按1：1的比例匹配接受传统人工全膝置换术（manual total knee arthroplasty， m-TKA）的患者。本研究已通过北京积水潭医院伦理委员会审批，所有患者均签署知情同意书。

研究纳入的患者分为两组，机器人手术组为接受机器人辅助下人工全膝关节置换术的患者，传统手术组为接受手工人工全膝关节置换术的患者。机器人手术组应用TIANVI 2.0机器人（天智航，中国）或MAKO机器人（史赛克，美国），使用假体类型为水泥固定CR或PS型假体，品牌包括Triathlon （史赛克，美国），Legion （施乐辉，英国）。传统手术组应用手工工具，股骨侧髓内定位，胫骨侧髓外定位，使用假体类型同样为水泥固定CR或PS型假体，品牌包括Triathlon（史赛克，美国），Legion（施乐辉，英国），GT（爱康，中国）。传统手术切口均为前正中髌旁入路，术中麻醉方式选择、关节周围镇痛、术后抗生素使用方案、静脉及口服镇痛方案、术后康复锻炼方案两组均一致。

研究通过医疗电子病历收集了两组患者的常规资料，包括年龄、性别、体重指数（body mass index, BMI）、术前诊断、合并症（高血压、冠心病、糖尿病）、手术侧别、ASA评分、术前关节功能评分。 关节功能评分采用美国西安大略和麦克马

斯特大学骨关节炎指数（The Western Ontario and McMaster Universities Arthritis Index，WOMAC）评分测量。WOMAC 评分包括整体评分和疼痛、僵硬、功能三个部分的评分。研究同时采集手术相关资料，包括手术时间、术中出血量和术后并发症发生情况。于 2024.10 至 2024.11 期间，研究团队对患者统一进行电话随访，明确患者术后对关节的整体满意度、关节功能评分和生活质量评分，并明确患者术后假体和关节相关结局。其中生活质量采用 EQ-5D-5L 量表测量。研究通过回顾性随访询问患者术前 EQ-5D-5L 评分。

统计分析：对于连续性变量，若数据符合正态分布，数据表述方式为平均数（标准差），若数据不符合正态分布，数据表述方式为中位数（四分位数）。对于连续性变量，研究采用双侧 t 检验进行统计。对于分类变量，数据表述方式为频数（百分比）并采用 Chi-square 或 Fisher’s 精确检验方法进行统计。研究计算了 WOMAC 评分和 EQ-5D-5L 评分在术前和随访的差值，，并依据已经建立的中国人群效用积分体系（Liu et al. 2014）计算效用值和相应质量调整生命年 (Quality-adjusted life years, QALYs)。研究应用 R 统计软件 (www.R-project.org/) 进行统计分析，双侧 p 值＜0.05 定义为有统计学显著差异。

三、结果

在研究期间，共有 247 名患者接受机器人辅助下人工全膝关节置换术，成功匹配 247 名接受手工人工全膝关节置换术的患者。其中机器人手术成功随访 202 名（81.8%）患者，传统手术组成功随访 199 名（80.6%）患者，两组随访率无显著差异。两组患者随访时间中位数（四分位数）为 18（7-31）个月。

患者一般资料可见表 1。研究纳入患者平均年龄（标准差）为 66.94（6.40）岁，82.04% 为女性。两组患者在基本特征和术中出血量无显著差异（p 值均 >0.05）。但机器人手术组的手术时间显著长于传统手术组（96.61 分钟 VS. 79.13 分钟，p<0.001）。

表 1. 机器人手术与传统手术组患者基本特征和术中情况

	机器人手术组（n=202)	传统手术组 (n=199)	P值
年龄，岁	66.94 (6.60)	66.96 (6.34)	0.96
性别，女	166 （82.18）	163 （81.91）	1.0
膝关节骨性关节炎	202	199	1.0
术侧，左侧	95 （47.03）	97 （48.74）	0.81
BMI, kg/m^2	28.29 (12.71)	26.60 (3.32)	0.072

高血压	88 （43.56）	99 （49.75）	0.40
冠心病	21 （10.40）	5 （2.51）	0.005
糖尿病	28 （13.86）	34 （17.09）	0.55
ASA 1级	70 （34.65）	71 （17.09）	0.60
手术时长，分钟	96.61 (20.50)	79.13 (18.65)	<0.001
术中出血量，毫升	56.35 (31.50)	56.26 (33.99)	0.98

Notes: BMI，体重指数。ASA，美国麻醉医师协会分级。

研究对机器人手术和传统手术的手术相关并发症进行统计，机器人手术组患者中有 1 名患者因术后活动过伸而行翻修手术治疗，其它术后并发症，包括假体松动、假体周围感染、关节相关住院、手术和门诊就诊均无显著统计学差异（表 2）。

表2 机器人手术与传统手术组患者假体与关节相关预后指标

	机器人手术组（n=202)	传统手术组 (n=199)	P值
假体翻修	1 （0.50）	0	1.0
假体松动	0	0	NA
假体周围感染	1（0.50）	0	1
关节相关住院	4（1.98）	0	0.14
关节相关手术	4（1.98）	0	0.14
关节相关门诊就诊	12（5.94）	10（5.03）	0.56

对于术后关节的满意度，机器人组整体满意度为 88.62%，传统手术患者满意度为 88.44%，整体满意度未有显著统计学差异（P=0.32，表 3）。但随访结果中可见机器人手术组中存在 3 个非常不满意的患者，而传统手术组并没有非常不满意患者。

表3 机器人手术组和传统手术组患者术后关节满意度差异

	机器人手术组（n=202)	传统手术组 (n=199)	P值
术后关节满意度			0.32
非常满意	112 （55.45）	125 (62.81)	
满意	67 （33.17）	51 (25.63)	
中性	15 （7.43）	19 (9.55)	
不满意	5 (2.47)	4 (2.01)	
非常不满意	3 (1.49)	0	

关于机器人辅助手术和传统手术患者术前、随访的 WOMAC 评分可见表 4。两组

患者术前 WOMAC 整体评分、疼痛、僵硬和功能评分无显著差异（p 值均 >0.05）。手术中，两组患者 WOMAC 整体和各项评分均显著改善，但差值无统计学差异（p 值均 >0.05）。将两组患者按照不同随访月份分组取 WOMAC 整体评分的平均数，可见两组间两连线图未间明显分层差异（图 1）。

表4. 机器人手术组和传统手术组患者WOMAC评分

	机器人组（n=202)	传统手术组 (n=199)	P值
WOMAC评分			
术前	45.40 (20.72)	45.99 (19.98)	0.77
随访	7.21 (11.11)	6.38 (10.63)	0.44
术前-随访差值	38.18 (21.52)	39.61 (19.88)	0.49
WOMAC 疼痛评分			
术前	54.48 (24.71)	52.46 (23.79)	0.41
随访	6.56 (12.28)	5.98 (11.64)	0.63
术前-随访差值	47.92 (25.24)	46.48 (24.33)	0.56
WOMAC僵硬评分			
术前	32.80 (29.94)	34.17 (28.52)	0.64
随访	7.43 (15.08)	6.85 (13.63)	0.69
术前-随访差值	25.37 (31.34)	27.32 (29.03)	0.52
WOMAC功能评分			
术前	44.21 (21.45)	45.48 (20.83)	0.55
随访	7.38 (12.12)	6.44 (11.33)	0.42
术前-随访差值	36.82 (22.48)	39.04 (20.93)	0.31

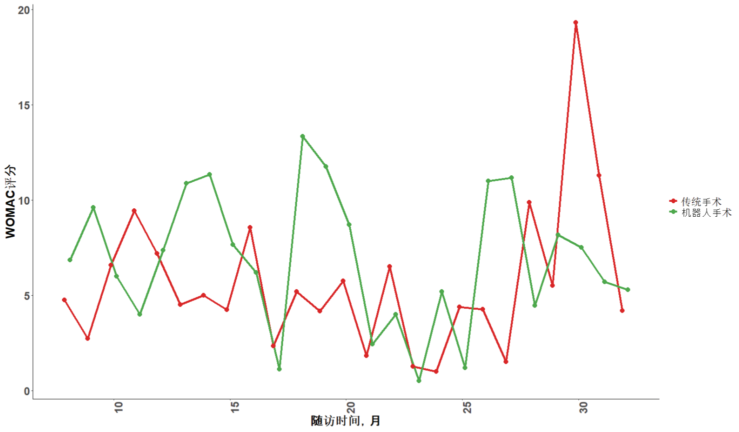

图 1. 机器人辅助手术和传统手术组患者WOMAC评分随术后时间变化

亚组分析：考虑到机器人手术的学习曲线，研究进一步依据随访时间对两种手术的手术时间进行分层分析。研究发现，传统手术组手术时间不随随访时长变化（$p>0.05$），但对于机器人辅助手术组，随着随访时间缩短，即机器人手术开展时间的延长，手术时间总体在缩短（$p<0.05$，表 5）。对于随访时间在 8-12 个月的患者，机器人辅助手术所需手术时间已与传统手术无显著性差异（$p=0.094$）。两组患者手术时长随时间的具体变化趋势亦可见图 2。

表5 机器人手术组和传统手术组不同随访时间段内手术时间（分钟）的变化

	机器人组（n=202）	传统手术组 (n=199)	P值
术后随访时间，月			
8-12	93.82 (14.83)	85.41 (24.48)	0.094
12-16	95.66 (18.14)	79.57 (19.72)	<0.001
16-20	87.11 (15.81)	77.04 （13.69）	0.019
20-24	99.77 (25.33)	78.96 (13.20)	<0.001
24-28	90.56 (22.42)	76.64 (15.47)	0.013
≥28	111.84 (20.37)	77.79 (20.21)	<0.001

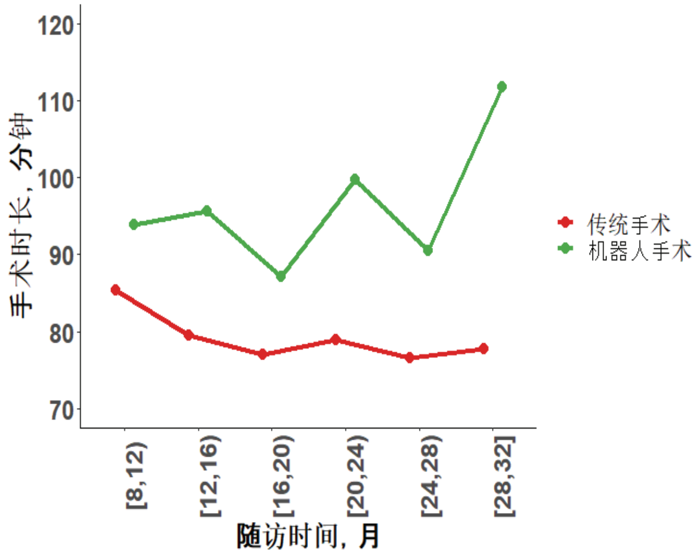

图2. 机器人手术组和传统手术组手术时长随随访时间的变化趋势

四、讨论

作为一项单中心回顾性和前瞻性相结合的队列研究，我们发现，机器人辅助全膝关节置换术与传统手术的中期临床疗效类似。随着机器人辅助技术的开展，机器人辅助手术的手术时间逐步缩短。

既往研究普遍认为在机器人辅助下的人工全膝关节置换术相对于手工方式人工全膝关节置换能够将假体更为精准地植入患者。前期研究通过对术后X线进行测量，发现机器人辅助下行TKA的患者术后整体力线、股骨侧、胫骨侧假体位置相对手工方式植入假体更为接近术前设计方案。同时前期研究也发现，相对于传统手术，机器人辅助手术的手术时间更长。本研究确实发现机器人辅助手术所花费的手术时间要显著高于传统手术，这与既往研究发现一致。手术时间延长可能与机器人辅助手术引入全新的器械、增加机器人操控人员，增加机器人安装调试及多名手术参与人员之间的配合有关。但机器人手术组的总时长并没有超过120 min，在理论上并没有增加感染的概率。同时，我们的研究发现随着手术开展的时间延长，手术量的积累，两组手术时间差异逐渐减少，在最近1年的时间内虽然机器人辅助手术组要更长一些，但两组之间已经没有显著的统计学差异。

我们发现，机器人辅助手术与传统手术相比在关节功能评分、生活质量评分和关节置换的整体满意度上无显著差异，该发现也与既往大部分研究结论相同（参考文献）。既往有研究发现机器人辅助手术在术后早期（＜6月），因其更少的软组织剥离量，患者关节周围炎症反应小，疼痛与功能回复更好，但本研究最短随访时间为7个月，并未涉及早期术后症状。本研究依据中期随访的结果，提示两种术式在中期临床疗效上无显著差异。

值得注意的是，本研究纳入了本中心最早接受机器人辅助手术的患者，术者可能需要克服新技术学习曲线问题。而对照组为同时期本中心其他有丰富手术经验术者（＞450 台/年，工作年限＞10年，一直选择手工方式进行TKA置换）的患者。这可能部分解释了为什么两组患者的临床疗效无显著差异。手工TKA疗效对于术者的经验及操作要求较高，学习曲线较长。通过机器人辅助进行TKA手术能够使术者在短期内获得媲美经验丰富掌握精湛技巧的手工置换术者的临床效果，显著缩短学习曲线。研究观察到机器人辅助手术组手术时间随技术的开展迅速缩短。随着机器人辅助手术的进一步推广，机器人辅助TKA的手术时间和临床疗效是否会进一步改善，甚至优于传统手术者需要未来研究进一步明确。

本研究存在一些局限。首先WOMAC评分为患者主观评分，我们通过电话随访患者，受研究条件限制获得数据受患者随访当时所处环境限制较多，部分患者回答问题不

清晰，对研究结果存在一定影响。其次，本研究中患者的随访率为81.8%，可能存在一定幸存者偏移的影响。最后，本研究的部分设计为回顾性研究，受到研究性质自身限制，可能存在研究者主观思想对随访结果的影响。

综上，研究纳入本中心使用机器人辅助行TKA治疗的初期患者，与同时期手工TKA匹配，两种术式术后临床疗效、关节满意度未发现明显差异。同时，随着机器人辅助手术工作量积累，机器人辅助手术总体手术时间也趋近于常规手工关节置换时间。研究提示使用机器人辅助行TKA手术能在短期内提升手术疗效，克服传统手术较长的学习曲线。本研究将继续经济学成本的评估，并构建长期预后模型来进一步明确机器人手术与传统手术相比的卫生经济性。

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人工智能与外科职业壁垒：
研究进展

潘聿航 易君健 周清源*

一、基准结果

在本节中，我们展示了主要研究结果，分析了达芬奇机器人引入对外科科室性别构成的影响。

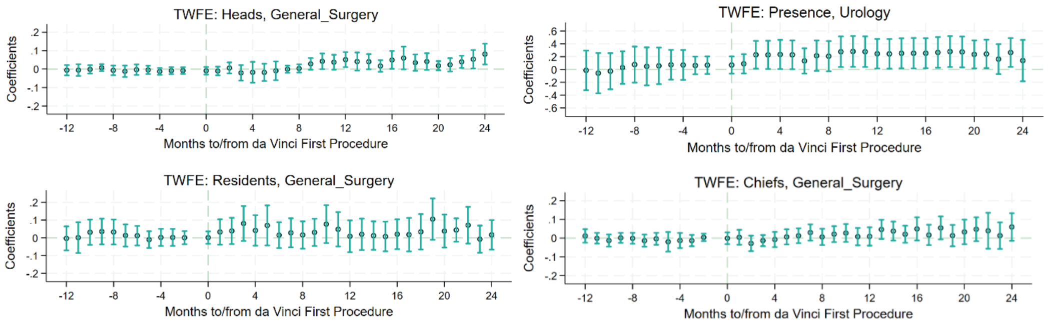

图1 距离首次使用达芬奇机器人手术的月份与女性比例

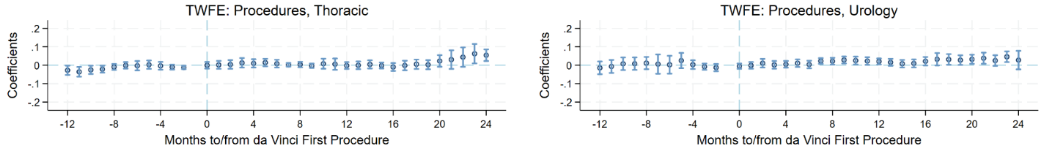

图2： 距离首次使用达芬奇机器人手术的月份与女性工作量

图 1 展示了各科室中女性比例以及女性科主任、主任医师、主治医师和住院医师的比例随时间的变化情况。我们将机器人引入前一个月的处理组和对照组的医院科室的差异作为参考基准。研究发现，在达芬奇手术系统引入后，女性相对比例在泌尿外科和普通外科有所上升，而在其他科室则相对保持稳定。此外，在普通外科中，

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* 潘聿航：北京大学全球健康发展研究院（E-mail:yhpan@pku.edu.cn）；易君健：北京大学国家发展研究院和全球健康发展研究院（E-mail:junjian@nsd.pku.edu.cn）；周清源：北京大学经济学院（E-mail:qingyuanzhou.econ@gmail.com）。

女性科主任和主任医师的比例有所增加，这表明女性获得了更多的晋升机会。然而，这些变化并未在机器人引入后立即发生，可能是因为科室需要时间进行人员调整。

图2展示了不同科室中女性手术量的变化趋势。结果显示，技术引入后，胸外科和泌尿外科中由女性外科医生执行的手术量有所增加。这表明技能偏向型技术变革可能改变了男女之间的比较优势，从而促进了女性更多进入外科领域。

二、研究进展

上一节的证据表明，某些科室中女性的比例和晋升机会有所增加。本节探讨与这一性别差距缩小相关的机制。具体而言，我们采用病例层面和医生层面数据，估计达芬奇机器人的引入对医生在资源使用决策和患者健康结果的分性别影响。

（一） 病例层面证据：分性别生产率

结果变量 为了测度医疗资源的使用情况，我们包括了三个主要结果变量：(i) 患者住院时间，(ii) 用于患者检查和检测的费用，以及 (iii) 本次住院期间的总医疗费用。为了减小极端值的影响，我们对医疗支出取对数。为了测度医疗质量，我们考察了两个主要的患者结果：(i) 患者30天内再次住院的指标——即患者在出院后30天内是否再次入院，以及 (ii) 患者是否在院内死亡的指标。

控制变量 我们的模型还包括一组患者控制变量，包括患者年龄段，性别，以及主要诊断的ICD-10（国际疾病分类，第十版）三位代码。

我们的实证模型如下：

$$Y_{ijt} = \sum_{k=-12,\, k\neq -1}^{k=24} \beta_k MR_{jt,k} + X_i\gamma + \delta_j + \eta_t + \epsilon_{jt} \#(1)$$

其中， Y_{ijt} 表示病例 i 在年份－月份 t，医院科室 j 中的医疗资源使用和医疗质量的测度。 t . $MR_{jt,k}$ 是虚拟变量，当年份－月份 t 距离医院科室 j 首次开展机器人辅助手术的时间为前（后）k 个月时取值为1，否则为0。X_i 表示患者风险调整因素。我们还加入了医院科室固定效应 δ_j 和年份－月份固定效应 η_t. ϵ_{jt}。是随机误差项。我们将标准误聚类在医院科室层面。

（二） 医生层面证据：分性别生产率

为探究机器人技术引入后女性外科医生获得更多晋升机会的原因，我们分别考察了机器人技术对男性和女性医生生产率的影响程度。

我们采用如下实证模型来估计医生使用机器人对其生产率和工作量影响的因果关系：

$$Y_{it} = \sum_{k=-12,\, k\neq -1}^{k=24} \beta_k MR_{it,k} + \delta_i + \eta_t + \epsilon_{it} \#(2)$$

其中，下标 i 表示医生，t 表示年份−季度。因变量 Y_{it} 代表医生 i 在 t 时期的患者院内死亡率、30 天内再入院率、平均住院天数和平均医疗费用，以及医生 i 在 t 时期实施的手术总数。我们关注的自变量 $MR_{it,k}$ 是虚拟变量，当年份−季度 t 距离医生 i 首次使用达芬奇手术机器人的时间为前（后）k 个季度时取值为 1，否则为 0。我们引入医生固定效应 δ_i 以控制医生间的异质性，即方程（2）的估计利用了医生个体内部的差异。最后，为误差项。标准误在医生层面进行聚类。

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

石茵，武子婷*

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，并处理变量，如转换家庭常住地信息、用CPI调整院内费用及确定医生经验；同时借调查问卷收集患者就医期间交通、住宿、营养、时间成本等。数据清理方面，已完成1730例院内数据清理，其中女性占42.3%，平均年龄60.8岁，64% 来自城市，机器人手术者占56.2%，且不同手术类型在住院天数、费用上有差异；74例院外数据清理也已完成，机器人手术患者部分非医疗费用和间接成本较低。未来项目组将继续收集完整数据，为后续分析机器人手术在胰腺恶性肿瘤治疗中的经济成本效益奠定基础。

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。

＊ 石茵，中南大学湘雅医院药学部；中南大学湘雅医院国家老年疾病临床研究中心；北京大学全球健康发展研究院，（shiyin910515@csu.edu.cn）；武子婷（通讯作者），北京大学全球健康发展研究院，（wuziting@pku.edu.cn）。

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。但从医院获取的变量需经过处理后进行统计分析，具体包括将通讯地址转变为城市或县镇或农村，以代替家庭常住地；将院内费用通过居民消费价格指数（Consumer Price Index，CPI）转换为2024年的价格；用每位患者手术当年之前的该术式的例数作为医生经验。

中国CPI的计算方式是，（一组固定商品按当期价格计算的价值/一组固定商品按基期价格计算的价值）×100。通货膨胀率=(现期CPI—基期CPI)/基期CPI*100%；通货膨胀率 =(现期物价水平 - 基期物价水平)/基期物价水平×100%。因此现期价格=通货膨胀率*基期物价水平+基期物价水平。本研究中，现期为2024年，基期为2013-2023年。具体通货膨胀率如表1所示。

表1 我国2013～2023年通货膨胀率

年份	CPI	通货膨胀率
2024	100.4	—
2023	100.2	0.001996008
2022	102	-0.015686275
2021	100.9	-0.004955401
2020	102.5	-0.020487805
2019	102.9	-0.024295432
2018	102.1	-0.016650343
2017	101.6	-0.011811024
2016	102	-0.015686275
2015	101.4	-0.009861933
2014	102	-0.015686275
2013	102.6	-0.021442495

通过调查问卷，我们获取了患者就医期间的交通费、住宿费、家属住宿或陪床费、患者营养费、患者时间成本（天）、家属时间成本（天）、是否请护工、护工日工资。本研究将患者和家属的时间成本按照一定的规则换算成货币。

对于退休年龄以下的护理人员，采用对应人群的工资标准进行测算，例如使用相同性别、年龄和受教育程度人群的平均小时工资（林国华 2020)。没有带薪工作的家庭主妇或退休人员，其小时工资往往不得而知。对于这类护理人员，可以应用当地时间价值研究中的标准。例如，Hanly P 等 (Hanly et al. 2013) 在使用机会成本评估与结直肠癌非正式护理相关的时间成本时，使用了 3 种方法：第 1 种，不考虑护理人员的就业状况，基于当地平均小时工资进行计算；第 2 种，从事有薪工作的护理人员参考按部门和性别划分的小时工资进行计算，非从事有薪工作的护理人员则参考当地最低工资进行计算；第 3 种，从事有薪工作的护理人员参考按职业和性别划分的小时工资进行计算，非从事有薪工作的护理人员则参考当地最低工资进行计算。在本研究中，具体而言，若患者 / 家属在就医期间有工作，则按照 2023 年中国城镇单位就业人员平均小时工资计算，若没有工作或在带孩子、做家务，则按照截止 2024 年 10 月全国最低工资标准计算。

全年工作时间计算标准来自我国政府官方网站，年工作日的计算方法是 365 天 -104 天（休息日）-13 天（法定节假日）＝ 248 天。工作小时数以月、季、年的工作日乘以每日的 8 小时。

就业人员年平均工资来自国家统计局，2023 年，全国城镇非私营单位和私营单位就业人员年平均工资分别为 120698 元和 68340 元。平均 94519 元。

有工作的患者或其家属每小时时间的货币价值计算方法是：94519/248/8=47.6 元 / 小时。

未就业人员工资依据全国最低工资标准计算，数据来自我国人力资源与社会保障部，本研究取全国小时最低工资标准的平均值，即 20 元 / 小时。

三、结果

（一）数据清理结果

已经清理完成 1730 名病例的院内数据，其中女性占 42.3%（732/1730）；平均年龄 60.8 岁（标准差：9.4）；64% 的患者来自城市（1108/1730）。行机器人手术者（包括机器人 + 腹腔镜、机器人 + 开腹）973 人，占全部病例的 56.2%；腹腔镜手术者（包括腹腔镜 + 开腹）149 人，占 8.6%；开腹手术者 504 人，占 29.1%。现有病例的院内例均总费用 122879.5（47758.1）元，手术费用 48179.0(26756.3) 元，住院天数 19（10）天。不同手术类型患者的例均住院天数、总费用和手术费如表 2 所示，机器人手术患者的住院天数相对其他术式更少，总费用和手术费更高。

表2 不同手术类型患者的例均住院天数、总费用和手术费（元）

手术类型	住院天数	总费用	手术费
腹腔镜	18.77	85652.28803	28323.69037
腹腔镜+开腹	23.89	118478.8566	42804.68293
机器人	16.73	119525.9664	57934.14641
机器人+腹腔镜	15.46	114223.1089	45608.77628
机器人+开腹	22.82	160547.6558	65960.4476
开腹	21.24	88360.36195	17172.21624
总计	18.61	106898.0196	41912.90313

已经清理完成 74 名病例的院外数据，患者时间成本 5777.2（3870.2）元；家属时间成本 7010.0（4486.0）元；例均交通费 4389.5（5917.9）元，患者住宿费 2675.1(4097.3)元,家属住宿、陪床费 2394.6(3977.5)元,患者营养费 585.5(1514.1)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，机器人手术患者的交通费、患者时间成本更少。

表3 不同手术类型患者的例均非医疗费用和间接成本（元）

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	5125	1500	225	625	7420.8	8505.6
机器人	3783	2446	2720	1187	5523	7193
开腹	6306	2795	2930	38	5731	6373
总计	4847	2488	2566	707	5777	7010

（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 74 份合格问卷的收集，问卷收集具体方式如下：

- 由 301 医院病房管床护士负责收集问卷信息。
- 已开始收集 9 月 2 日起出院的胰腺恶性肿瘤患者，接受了胰腺切除手术的即可纳入，机器人、腹腔镜、开腹各 80 例。
- 患者或家属填写均可。
- 为保证所收集信息的准确性和尽量减少对患者和临床的打扰，经与临床医生沟通，题目简单易懂，数量较少。

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1730例胰腺恶性肿瘤患者的信息抄录。

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我国高科技卫生技术分布宏观影响因素及其空间溢出效应:基于手术机器人的证据

陈婷，敖露，潘聿航，潘杰*

摘　要　在经济快速发展的背景下，人民的卫生服务需求日益增长，呈现出高层次、多样化的局面，高科技的医疗卫生技术是推动医疗高质量发展的重要举措。然而，我国卫生技术的扩散与分布存在诸多信息灰箱，公平性面临挑战。本研究以手术机器人为研究对象，探索高科技卫生技术在我国扩散差异化的原因，为文献和相关监管政策提供实证基础。在前三个季度的分析基础上，本部分研究的研究内容主要分两个板块，首先是是影响因素分析，基于区域层面构建面板回归分析宏观因素（PEST）对卫生技术扩散的影响；然后在各影响因素的基础上分析技术的空间溢出效应，探究卫生技术扩散的时空滞后性。结果显示，政治、经济、社会和技术因素均会对我国手术机器人的扩散分布具有显著的影响。地区卫生总费用的占比、高等教育水平、市场竞争程度和综合创新能力的提升有助于创新卫生技术的扩散和进步；卫生技术的扩散具有正向的空间溢出效应，市场竞争对卫生技术扩散的影响同样具有地区间的溢出效应。高科技卫生技术的扩散具有地区和社会经济的不平等性，地区对卫生医疗的重视程度、医疗市场的良性竞争和地区本身的创新环境和创新能力均有利于创新卫生技术的扩散，地区的技术进步也将带动周围地区的技术进步，产生良性循环。

一、背景

从1978年的“阿拉木图宣言”提出“2000年人人享有初级卫生保健”到2015年的联合国特别峰会提出“2030年实现可持续发展目标”（其中包括保障“全民全生命期健康”），国际社会始终倡导的一个核心理念即人人公平地享有健康(United Nations 2015)。自1978年，我国开始以市场为导向的经济改革后，我国为实现全民健康覆盖作出众多实质性的努力，特别是基本医疗保险和基本公共卫生服务的全民覆盖(Tang et al. 2008)。习近平总书记曾多次谈及健康公平问题，指出让广大人民群众享有公平可及、系统连续的预防、治疗、康复、健康促进等健康服务(the

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*　陈婷，四川大学华西公共卫生学院/四川大学华西第四医院 HEOA Group；敖露，四川大学华西公共卫生学院/四川大学华西第四医院 HEOA Group；潘聿航，北京大学全球健康发展研究院。通信作者：潘杰，四川大学华西公共卫生学院/四川大学华西第四医院 HEOA Group E-mail：panjie.jay@scu.edu.cn

Xinhua News Agency 2024)。

因此，“健康公平”的概念越来越受到关注。虽然已发表的研究报告了我国国家层面健康状况 (Zhang and Kanbur 2005; Tang et al. 2008)、卫生保健服务 (National Health Commission 2021; Tang et al. 2008)、医疗保险 (Yang et al. 2021)、卫生资源（包括专业卫生人员）(Liu et al. 2016) 等方面的不公平，但只有少数研究关注到高新技术医疗设备分布的公平性。特别地，我国关于两项常见高新医疗技术设备（计算机断层扫描即CT和磁共振成像即MRI）的研究发现，在2004年之前，我国这两项技术在全国的分配相对公平，而2006年之后的研究结果却显示，高新技术设备的公平性较低，且其分布与地区社会经济水平显著相关 (He, Yu, and Chen 2013)。虽然我国在基本卫生服务的全民覆盖上实现了重大突破，但是优质资源的集中化始终难以避免。2024年，中共中央发布《关于进一步全面深化改革 推进中国式现代化的决定》，强调深化医药卫生体制改革应“促进优质医疗资源扩容下沉和区域均衡布局”(the Central Committee of the Communist Party of China 2024)。

手术机器人作为目前高精尖前沿医疗卫生技术的代表之一，自2006年首例达芬奇手术机器人引入我国以来，基于技术效果优势和社会效益等因素，其在我国的扩散得到了蓬勃发展。然而，与国际相比，我国仍在手术机器人技术扩散的早期。研究表明，自2000年手术机器人问世，截至2015年美国超过50%的医院配备有手术机器人并展开手术，但我国自首次使用手术机器人以来，截至2021，同样经历了15年的时间，仅有224家医疗机构配备手术机器人，占全国医院数量的0.61%，可以预见该技术在我国仍有较大的市场空间。另外，机器人辅助手术开展可部分缓解医疗欠发达地区对高质量人才的紧缺。手术的操作经验往往是影响外科医生手术质量的决定因素之一 (Sosa et al., n.d.)。手术机器人的重要临床优势包括缓解外科医生的操作环境（如需要长久站立和手部用力）、全方位的高分辨率三维视野、消除手部颤抖以及实现外科医生设想的精确操作等 (Lanfranco et al. 2004)，因此更容易缩短临床医生的“学习曲线”，让相对缺乏临床经验的年资轻的医生更容易达到其“高水平”状态 (Frieberg et al. 2024)，因此有益于打通优质医疗服务下沉的技术机制途径，以此推动高质量服务资源的公平化。

区域因素，如经济人口学因素被认为是影响技术扩散的不公平分布的重要驱动 (Varabyova et al. 2017)，本研究进一步依托手术机器人这一领先的高先进卫生技术，探索技术资源配置的影响因素。美国 (Mohanty et al. 2022)、瑞士 (Stalder et al. 2024)、澳大利亚和新西兰 (Royal Australasian College of Surgeons

2021) 等发达国家探讨了手术机器人分布的不公平性及其成因，发现部分区域和机构因素在卫生技术的采纳下呈现异质性，例如区域的经济水平、人口地理位置、对创新的开放程度，以及市场的竞争程度等均会影响卫生技术的分布差异 (Varabyova et al. 2017)。目前，中国还缺乏相关的实证研究。中国医疗卫生市场具有集中规划配置和市场协调的双重作用，该模式也逐渐被国际学者予以认可 (Cutler 2024)，在此机制下市场和相关因素究竟发挥着怎样的作用，还有待探索。

同时，本系列研究的前期分析发现了卫生技术的配置具有空间聚集性，提示一个地区的卫生技术采用，不仅能造福当地人群，也会带动周围地区技术的提升，产生空间溢出效应。同时，一个地区的技术情况也可能会受到该地区之前水平的滞后影响，因此本研究创新性地利用空间面板模型量化卫生技术扩散的溢出效应。因此，本研究可为推动我国高科技的优质医疗资源的下沉和高质量发展提供实证的经验与证据。并为文献和相关监管政策提供实证证据和基础。

二、数据与方法

数据上。本研究以我国手术机器人的引入和使用作为研究对象，数据来源于占有目前手术机器人的市场份额绝对优势（占中国大陆部分类别手术机器人业务量 90% 以上）的机器人服务商的经营数据。第一，地区数据如常住人口和主要来源于《中国统计年鉴（2008-2022）》和各省份统计年鉴。区县的人口数据根据 WorldPop 1*1km 人口栅格数据聚合到区县区划水平所得。按照国家统计局的地区分组，将我国除台湾省、香港和澳门特别行政区以外的 31 个省、自治区、直辖市划分为东部（北京、天津、河北、山东、辽宁、上海、江苏、浙江、福建、广东和海南共 11 个省份）；中部（山西、吉林、黑龙江、安徽、江西、河南、湖北和湖南共 8 个省份）和西部（内蒙古、广西、重庆、四川、贵州、云南、西藏、陕西、甘肃、青海、宁夏和新疆共 12 个省份)3 个区域。第二，卫生相关数据来自于《中国卫生统计年鉴（2008-2012）》《中国卫生和计划生育统计年鉴（2013-2017）》《中国卫生健康统计年鉴（2018-2022）》。区域创新能力来自于相应年份（2007-2021 年）《中国区域创新能力评价报告》；区域教育水平则来源于《中国教育统计年鉴》。为定位医院的地理位置和计算机构间的距离以构建距离权重矩阵，本部分利用医院名称通过医院官方网站确定医院的具体地址信息，通过高德地图开放平台获取的 API 提取其所对应的地理经纬度信息。

通过前期序列研究，可以看到我国卫生技术资源的配置是具有地区差异的，在人均和地均的尺度上都分布不平等，和地区的经济发展水平、政策资源、健康需求

和市场规模等因素都可能存在相关性。本部分进一步使用2007-2022年的面板回归模型探究影响卫生技术引入的宏观经济因素的具体影响，考虑到手术机器人作为高科技的医疗卫生技术，目前的潜在消费市场仍是各地区的三级医院（截至2022年在引入手术机器人的医院中，全部为三级医院），因此本部分研究在选取相关市场因素时，主要考虑高等级医疗机构的医疗卫生市场。

在相关因素的选择上，参考文献回顾和前期研究，本研究主要利用PEST宏观环境分析模型构建相关分析。PEST理论模型组成有四个部分：政治（Political）、经济（Economic）、社会（Social）和技术（Technological），该模型框架是最常用的宏观环境分析工具之一，用以分析影响行业或企业发展的各种宏观力量(Aguilar 1967)。因此，本研究的自变量主要包括政治因素：政府投入卫生总费用，经济因素：地区的经济水平，以人均GDP为代理变量（采用居民消费指数CPI调整通货膨胀的影响）；社会文化因素：地区的需求因素，本研究主要为地区的健康需求，以外科住院人次为代理变量，同时以居民教育程度，反映居民对区域创新技术可能的需求层次(QIongqi Xiao and Kangwang, n.d.)；另外也加入了医疗市场竞争程度的指标，市场中供给者的数量常用于衡量市场竞争强度，通常情况下，供给者数量越多，市场竞争越激烈。在医院竞争最初的一些研究中，医院数量常用来衡量医院市场竞争强度(Gaynor and Town 2011)。此后，一些学者在医院数量指标的基础上，进一步提出了其它指标，包括三级医院数量、新增医院数量等(Lu et al. 2021)，本研究以地区“三级医院数量”为市场规模和市场竞争的代理变量进行分析。技术因素来源于《中国区域科技创新能力评价报告》其中的综合科技创新水平指数。

PEST宏观环境分析模型

方法上。首先，考虑到研究的数据情况，影响因素分析主要采用混合横截面线性回归模型（OLS）、固定效应线性回归模型（FE），以及固定效应负二项回归模型

（NB-FE）分别进行建模估计。由于卫生技术资源的数据为面板资料（平衡面板），因此本研究主要采用面板数据分析策略进行相关探索分析。面板数据有不同于横截面数据的分析策略及方法，主要包括固定效应及随机效应回归模型，其具有一些优势：首先，通过引入个体固定或随机效应，可以有效解决遗漏变量问题，当存在不可观测的个体差异时，固定效应模型能够捕捉这些差异，从而减少模型中的误差项，提高估计的准确性；同时，由于面板数据同时包含横截面和时间序列的信息，这使得固定效应模型能够提供更多关于个体动态行为的变异，模型可以分析个体在不同时间点的变化和动态过程。基本模型如下：

$$(1)\quad Y_{jt} = \boldsymbol{X'\beta} + \alpha_j + \varepsilon_{jt}\text{，其中}$$

$$\boldsymbol{X'} = (1, x_1, x_2, x_3, \dots, x_n)\text{，}\ \boldsymbol{\beta} = \begin{pmatrix} \beta_0 \\ \beta_1 \\ \beta_2 \\ \beta_3 \\ \dots \\ \beta_n \end{pmatrix}$$

其中，j 代表省市，t 代表时间。Y 代表卫生技术资源的代理变量。X 代表自变量矩阵，包括地区经济人口因素，健康需求因素和市场规模因素，以及添加了年份哑变量用来控制不可观测的时间固定效应。α 代表与省市相关且在时间尺度上恒定的但不可观测的个体固定效应，ε 为扰动项。向量 β 代表自变量矩阵 X 的系数。其中，β_0 为截距项，β_1, β_2,…, β_n 为自变量（包括时间固定效应）的系数。同时，考虑到卫生技术资源的的代理变量，即手术机器人的配置数量，只能取非负的整数，无法满足普通线性回归要求的因变量服从或近似服从正态分布，会严重的异方差问题和估计的有偏，因此本研究使用当因变量的取值只能是非负整数时，作为是较好的选择的泊松回归模型（当均值与方差相等）或负二项回归模型（Wooldridge 2010; Coxe, West, and Aiken 2009）（过离散数据，即方差远大于期望）。

其次，本研究进一步探索在控制了相关宏观影响因素之后，卫生技术扩散的空间溢出效应，即各省市对卫生技术的采纳可能会相互影响，特别是周围的省市。主要采用空间面板模型进行相关分析。常用的空间面板模型包括空间自回归模型（Spatial autoregression model, SAR）及空间杜宾模型（Spatial durbin model, SDM）。SAR 是在公式 1 的基础上进一步加入空间滞后项的因变量；如果在 SAR 的基础上，进一步加入空间滞后自变量，即为 SDM。

空间面板模型的一般形式如下：

$$（2）\mathrm{Y}_{jt} = \boldsymbol{X}'\beta + \gamma \boldsymbol{w}_j' y_t + \boldsymbol{h}_j' \boldsymbol{X}' \lambda + \alpha_j + \varepsilon_{jt}$$

其中，$\varepsilon_{jt} = \rho \boldsymbol{w}_j' \varepsilon_t + \epsilon_{jt}$

$$\boldsymbol{X}' = (1, x_1, x_2, x_3, \dots, x_n)，\beta = \begin{pmatrix} \beta_0 \\ \beta_1 \\ \beta_2 \\ \beta_3 \\ \dots \\ \beta_n \end{pmatrix}，\lambda = \begin{pmatrix} \lambda_0 \\ \lambda_1 \\ \lambda_2 \\ \lambda_3 \\ \dots \\ \lambda_n \end{pmatrix}$$

其中，j 代表省份，t 代表时间，Y 代表卫生技术资源。X 代表自变量矩阵。γ 代表空间滞后被解释变量的系数，代表自变量矩阵 X 的系数，λ 代表空间滞后解释变量的系数。α 代表医院相关的在时间尺度上恒定但不可观测的个体固定效应，代表随机扰动项，w、h 为空间权重矩阵。扰动项的空间相关性关系着是否采用空间误差模型（SEM），若 $\rho w_j' \varepsilon_t$ 为 0，提示不需要采用 SEM，此时，当 $h_j' X' \lambda$ 为 0，$\gamma w_j' y_t$ 不为 0 时，公式 2 为空间自回归模型（SAR）；当 $\gamma w_j' y_t$ 和 $h_j' X' \lambda$ 皆不为 0 时，公式 2 则为空间杜宾模型（SDM），若 $\rho w_j' \varepsilon_t$ 也不为 0，则采用空间杜宾误差模型（SDEM）。同时，LeSage 等人提出了选择合适模型的贝叶斯方法，可以计算各个空间面板模型的后验概率以筛选最佳的回归模型 (LeSage and Parent 2007)。

医疗机构的标准地址收集于各由各机构官方网站查询，经纬度坐标使用高德开放平台进行转换。本研究的数据分析和作图软件为 R 4.2.3。

三、结果

根据 PEST 理论模型，本部分研究的自变量主要包括政治因素：政府投入卫生总费用，经济因素：地区的经济水平，以人均 GDP 为代理变量（采用居民消费指数 CPI 调整通货膨胀的影响）；社会文化因素：地区的需求因素，本研究主要为地区的健康需求，以外科住院人次为代理变量，同时以居民教育程度，反映居民对区域创新技术可能的需求层次；同时也加入了医疗市场竞争程度的指标，市场中供给者的数量常用于衡量市场竞争强度，通常情况下，供给者数量越多，市场竞争越激烈。同时，以地区“三级医院数量”为市场规模和市场竞争的代理变量进行分析。技术因素来源于《中国区域科技创新能力评价报告》其中的综合科技创新水平指数，各变量的

描述性统计见Table 1，其中，高等教育水平＝地区在校高等学校在校人数／地区总人口数＊万人，即每万人居民中在校的高等学校的专科、本科以及研究生数量。

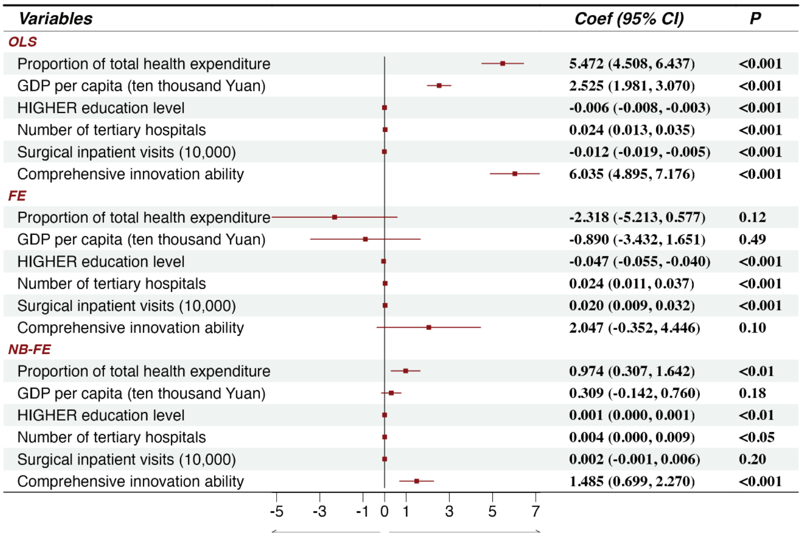
TABLE 1—DESCRIPTIVE STATISTICS OF VARIABLES

Variables	n	Mean	SD	Median	IRQ_1	IRQ_3
Number of surgical robots	465	1.91	3.86	0.00	0.00	2.00
Surgical robot usage	465	601.10	1310.42	0.00	0.00	527.00
Proportion of total health expenditure	465	6.39	1.91	6.12	4.96	12.97
GDP per capita (ten thousand Yuan)	465	4.96	2.91	4.33	2.94	6.32
HIGHER education level	465	233.44	103.21	225.47	182.10	280.47
Number of tertiary hospitals	465	64.34	46.11	53.00	35.00	85.00
Surgical inpatient visits (10,000)	465	89.92	67.36	73.57	41.38	119.62
Comprehensive innovation ability	465	28.91	10.59	26.30	21.22	31.28

Notes: HIGHER education level = Number of students in colleges and universities in the region /the total population of the region * 10 000, that is, the number of colleges and universities and graduate students per 10 000 residents; Proportion of total health expenditure = proportion of total health expenditure in regional GDP

首先，本研究对随机效应线性回归模型（RE）和固定效应线性回归模型（FE）进行豪斯曼检验，结果显示，$p<0.01$，提示具有在时间尺度上恒定不变的个体效应与自变量相关。因此，本研究采用固定效应模型进行面板数据分析。进一步地，由于医疗技术配置的代理变量为手术机器人数量，只能取正整数的计数资料，进一步地，对过度分散参数进行假设检验，因变量的均值为1.91，方差为14.87，方差远大于均值（14.87>1.91）。检验可发现过度分散参数为1.331，$p<0.001$，提示分布过离散化，需要利用负二项回归模型进行分析。同时，经过共线性方差膨胀因子（VIF）检验，所选入的所有自变量的方差膨胀因子均小于4.5（VIF<4.5），提示回归不存在严重的共线性问题。

Figure 1 展示了各维度的宏观因素的估计系数及其95%的置信区间。其中，自上而下分别展示的是混合横截面线性回归模型（OLS）、固定效应线性回归模型（FE），以及固定效应负二项回归模型（NB-FE）的估计结果。以固定效应负二项回归模型（NB-FE）为最终模型，可以看到，政治因素：卫生总费用占总GDP占比对卫生技术的配置具有显著的正向影响，当卫生总费用的占比占增加10%，手术机器人的配置平均增加9.8%，即政府和社会对卫生领域越重视投入越多，其卫生技术的配置高的可能性越大。在经济因素方面，控制其它因素以及地区与年份的固定效应后，人均GDP水平对卫生技术扩散的促进作用不显著。在一般线性回归和固定效应模型中，地区的高等教育水平越高，卫生技术的扩散反而更小，但是在固定效应模型的负二项回归中，高等教育水平与卫生技术的扩散呈显著的正相关，提示地区教育水平越高，更有可能对高科技的先进卫生技术进行引入。三级医院的数量代表了医疗卫生市场的规模和竞争程度，结果显示，医疗卫生市场的竞争越大，其引入配置高科技卫生技术的概率更高。另外，在控制和地区个体和时间变量后，地区的综合创新能力与卫生技术的扩散呈现显著的正相关性，地区综合创新能力提升10%，卫生技术资源配置可升高14.8%。



Variables	Coef (95% CI)	P
OLS		
Proportion of total health expenditure	**5.472 (4.508, 6.437)**	**<0.001**
GDP per capita (ten thousand Yuan)	**2.525 (1.981, 3.070)**	**<0.001**
HIGHER education level	**-0.006 (-0.008, -0.003)**	**<0.001**
Number of tertiary hospitals	**0.024 (0.013, 0.035)**	**<0.001**
Surgical inpatient visits (10,000)	**-0.012 (-0.019, -0.005)**	**<0.001**
Comprehensive innovation ability	**6.035 (4.895, 7.176)**	**<0.001**
FE		
Proportion of total health expenditure	**-2.318 (-5.213, 0.577)**	**0.12**
GDP per capita (ten thousand Yuan)	**-0.890 (-3.432, 1.651)**	**0.49**
HIGHER education level	**-0.047 (-0.055, -0.040)**	**<0.001**
Number of tertiary hospitals	**0.024 (0.011, 0.037)**	**<0.001**
Surgical inpatient visits (10,000)	**0.020 (0.009, 0.032)**	**<0.001**
Comprehensive innovation ability	**2.047 (-0.352, 4.446)**	**0.10**
NB-FE		
Proportion of total health expenditure	**0.974 (0.307, 1.642)**	**<0.01**
GDP per capita (ten thousand Yuan)	**0.309 (-0.142, 0.760)**	**0.18**
HIGHER education level	**0.001 (0.000, 0.001)**	**<0.01**
Number of tertiary hospitals	**0.004 (0.000, 0.009)**	**<0.05**
Surgical inpatient visits (10,000)	**0.002 (-0.001, 0.006)**	**0.20**
Comprehensive innovation ability	**1.485 (0.699, 2.270)**	**<0.001**

FIGURE 1. ANALYSIS OF INFLUENCING FACTORS OF HEALTH TECHNOLOGY INTRODUCTION

Notes: (1) The vertical axis shows the estimation results of mixed cross-sectional logistic regression (OLS), fixed effect linear regression (FE) and fixed effect negative binomial regression (NB-FE) from bottom to top; (2) For the dependent variable regression model, the average marginal effect is shown; (3) Because robust standard errors could not be used for NB-RE and NB-FE, common standard errors were used to calculate the 95% confidence intervals of the estimated coefficients, while robust standard errors were used for other models. (3) HIGHER education level = Number of students in colleges and universities in the region /the total population of the region * 10 000, that is, the number of colleges and universities and graduate students per 10 000 residents; Proportion of total health expenditure = proportion of total health expenditure in regional GDP.

本部分进一步利用动态空间面板模型探索时空效应所带来的潜在影响，考虑到空间面板回归模型尚无法直接与限值因变量回归模型结合使用，故本部分将医疗技术配置的代理变量进行数据转换，并在对数线性回归模型的基础上进行空间面板回归分析。首先，利用贝叶斯方法选择更合适的空间动态面板模型 (LeSage and Parent 2007; James P. LeSage 2014)。由于未有相关研究和经验对手术机器人扩散的先验概率提出建议，再考虑因变量为计数资料，因此本部分采用基于贝塔分布（Beta Distribution）的先验构建相关加入时空滞后项（动态）的时空固定效应面板模型进行模型选择，以模型的贝叶斯后验概率筛选最佳的空间模型，如Table 2结果显示，SDEM模型的边际后验概率（Log-marginal posterior）和模型概率（Model probability）均为最大。因此，本部分研究以动态空间杜宾误差模型（Dynamic SDEM）作为最终模型进行分析。

TABLE 2—MODEL SELECTTION

Model	SAR	SDM	SEM	SDEM
Log-marginal posterior	-1433.22	-1432.52	-1435.65	-1432.24
Model probability	0.1735	0.3496	0.0151	0.4617

Notes: Log-marginal posterior represents the likelihood of the log-transformed marginal posterior. Model probability represents the relative probability of selecting a model.

Table 3为卫生技术扩散的空间溢出效应的估计结果。其中，列（1）为不考虑空间效应的固定效应模型，（2）和（3）分别展示了静态杜宾固定效应模型和动态杜宾固定效应模型。结果显示，卫生技术的扩散具有正向的空间溢出效应，即一个地区卫生技术的引入会对周围地区的卫生技术引入起到一个正向的影响。同时，地区卫生技术引入的不仅受到周边其他地区当前卫生技术引入数量的影响，还受到自身及邻近地区过去卫生技术引入累积效应的影响，且这种时空交织的相关性，会使得卫生技术的进步和扩散在空间和时间两个维度均呈现出复杂且丰富的动态变化。同时，这种正向效应在地区间传递时，还对本区域产生正向反馈效应，从而形成一个动态的循环互动过程。在其它宏观影响因素中，值得说明的是，三级医院数量在考虑到卫生技术的时空变化后也始终呈现出与卫生技术引入的正的相关性，提示其作为“医疗市场竞争”的代理变量，强调了市场竞争早在卫生技术扩散过程中的重要性。

Table 3—Spatial Spillover Effect Estimation

Variables	（1） Fixed Effect Model	（2） SEM	（3） SDEM
Surgical Robot$_{t-1}$			1.18***
			（0.03）
Surgical Robot$_{t-1}$*W			0.22*
			（0.10）
Proportion of total health expenditure	-2.32	-1.71	-0.13
	（1.48）	（1.38）	（0.80）
GDP per capita (ten thousand Yuan)	-0.89	-1.77	-1.57*
	（1.30）	（1.26）	（0.77）
HIGHER education Level	-0.05***	-0.04***	0.00
	（0.00）	（0.00）	（0.00）
Number of tertiary hospitals	0.02***	0.02***	0.01***
	（0.01）	（0.01）	（0.00）
Surgical inpatient visits (10,000)	0.02***	0.00	-0.00
	（0.01）	（0.01）	（0.00）
Comprehensive innovation ability	2.05	1.76	0.57
	（1.22）	（1.13）	（0.66）
Proportion of total health expenditure*W		7.02*	-2.12
		（0.01）	（1.64）
GDP per capita *W		7.88**	-0.44
		（2.47）	（1.50）
HIGHER education Level *W		0.01	0.00
		（0.01）	（0.01）
Number of tertiary hospitals *W		-0.08***	0.01
		（0.02）	（0.01）
Surgical inpatient visits *W		0.07***	-0.01
		（0.01）	（0.01）
Comprehensive innovation ability*W		-10.17***	1.73
		（2.35）	（1.42）

Region effects	Yes	Yes	Yes
Time effects	Yes	Yes	Yes

Notes :(1) Surgical Robot$_{t-1}$ represents the lag term of health technology numbers, and Surgical Robot$_{t-1}$*W represents the interaction term between the lag of health technology numbers and the spatial matrix; (2) Proportion of total health expenditure = proportion of total health expenditure in regional GDP; The unit of number of surgical inpatients was 10,000 people. HIGHER education level = number of institutions of higher learning in the region/total population of the region * 10 000 people

四、讨论与总结

在本次分享中，本研究结合相关经典文献和理论，提出促进区域创新卫生技术扩散的宏观影响因素框架和的空间溢出效应假说，并基于2007-2021年中国31个省份数据，采用前沿的负二项面板固定效应模型和动态空间杜宾模型，实证分析了以手术机器人作为高科技医疗技术代表，区域卫生技术进步的影响机制与空间溢出效应。研究发现，政治、经济、社会和技术因素均会对我国手术机器人的扩散分布具有显著的影响，卫生技术的扩散具有空间溢出效应。地区卫生总费用的占比、高等教育水平、市场竞争程度和综合创新能力的提升均有助于创新卫生技术的扩散；同时，卫生技术的扩散具有正向的空间溢出效应，地区的技术进步将对周边区域的技术进步具有带动作用，市场竞争对卫生技术扩散的影响同样具有地区间的溢出效应。

根据文献回顾，目前关于创新高科技卫生技术扩散的影响因素研究往往只考虑到某一方面（如医疗市场竞争、地区创新能力等），或者多停留在定性和理论层面，尚缺乏实证证据综合性地探索卫生技术扩散的影响因素分析，同时从空间相关性和空间溢出效应视角的探讨尚无，本研究的结果从实证层面证实了领域内的相关理论假设，并进一步创新性提出了卫生技术扩散的空间溢出效应，为卫生技术进步和扩散的相关理论研究政策制定提供新的理论视角和证据基础。

高科技卫生技术的扩散具有地区和社会经济的不平等性，地区对卫生医疗的重视程度、医疗市场的良性竞争和地区本身的创新环境和创新能力均有利于创新卫生技术的扩散，地区的技术进步也将带动周围地区的技术进步，产生良性循环。本研究以地区卫生总费用占地区总GDP的占比作为地区对医疗卫生领域重视程度和政策倾向的代理变量，其包括了政府卫生支出、社会卫生支出、个人卫生支出和用于卫生科研等相关领域支出与投入，该变量与以往研究所采用的“人均卫生支出总额”相比考虑到地区本身的发达水平（Varabyova et al. 2017），更能反映地区对卫生领域

的重视程度，实证结果验证了卫生领域的投入与技术进步的相关性。高等教育水平一方面可以反映地区对创新技术的需求层次，同样在研究中往往也作为一个地区开放程度的反映，即地区的创新和创新采用的开放环境，结果显示，地区高等教育水平的提升与地区技术进步呈现出正的相关性。同样的，地区的综合创新能力，本身代表了区域对创新技术的倾向、投入和接纳性（QIongqi Xiao and Kangwang, n.d.），技术创新与技术引进是相辅相成的，技术引入为创新提供了基础和资源，在此基础上创新技术的才能实现技术追赶和可持续的技术进步和良性技术发展模式。

医疗卫生市场的竞争对医疗卫生服务的影响一直以来受到颇多争议。一方面，与其他市场一样，竞争作为市场机制最主要的体现形式，有效的竞争可促进市场中的产品和服务具有更低的价格、更高的质量和效率，从而提升消费者的福利；另一方面，由于医疗卫生市场的特殊性（如信息不对称等），影响医疗市场中竞争的活动和效果，可能导致市场机制发挥失灵，从而造成不必要的福利损失（Mankiw 2020）。由于医疗领域的特殊性，在大部分情况下患者无法直接获取有关医院服务质量及医院服务能力的相关信息，也无法如一般商品市场中一样通过重复消费等方式弥补信息鸿沟。因此，在医疗卫生市场中，患者（技术使用的消费者）往往倾向于依靠医院所拥有的先进医疗技术作为评价医院服务能力的依据（Aggarwal et al. 2017; 2018; Lu et al. 2021），从而导致医疗机构也倾向于引入高科技卫生技术以彰显其医疗服务能力和水平，吸引更多患者。本研究的实证分析表明，医疗市场的竞争提高与创新技术的扩散相关，且该作用具有空间溢出效应（不仅影响本市场，对周围市场的技术进步也具有促进作用）。然而，引进先进医疗技术的成本是高昂的，在不合理的经济激励及按项目付费的支付方式下，医院可能采取不合理的行为，如诱导需求，将配置成本转嫁给患者，增加患者医疗费用（Pan, Qin, and Hsieh 2016; Aggarwal et al. 2017），因此考虑此方面，需要政府与学术界加强进一步的监管和评价体系的管理研究与建设。同时，本研究的实证分析是基于省级层面，对医疗卫生市场的划分相对粗略，急需统计层级更为精细的研究验证对于卫生技术扩散的真实世界现况和规律。

高科技及先进医疗设备是医疗技术的主要体现形式，也是医院在技术投入方面的主要聚焦点。目前，相比于欧美、澳大利亚等发达国家，我国手术机器人的技术配置量和相对使用量均还十分缺乏，手术机器人的市场空间较大，在技术的大规模普及之前，需加强对技术分布公平性的规划和关注，特别是区域内的差异愈发严峻，聚集分布的异常点提示了客观上的技术缺口，同时技术的先行者可为后采用者提供技术的实证经验，为技术的“适宜”扩散提供因地制宜的证据基础。

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手术机器人卫生技术评估概述

张田甜*

摘　　要　本文全面探讨了手术机器人的卫生技术评估，首先介绍了卫生技术评估的定义，强调其在为各层次决策者提供科学信息和决策依据方面的重要性，随后以新旧两朵价值之花介绍卫生技术的价值维度，并着重说明了涵盖手术机器人在内的医疗器械的价值维度。接着，文章深入分析了手术机器人在IDEAL框架下的评估路径，包括从设备开发者、临床医生、患者以及医疗卫生系统的不同视角出发的三个阶段评估建议。此外，文章还详细讨论了手术机器人HTA过程中需特别注意的事项并给出了相应建议，如证据纳入与排除、患者与医生视角的考量、学习曲线效应、成本分配、分析方法、时间范围、组织影响以及增量创新等，旨在克服评估挑战，提高评估结果的准确性和可靠性。最后，文章再次强调了手术机器人HTA的复杂性和重要性，并展望了未来评估方法的创新和发展，以期为医疗决策提供更有力的支持，推动手术机器人技术的合理应用和医疗服务质量的提升。

一、卫生技术评估

（一）定义

2020 年，世界卫生组织联合数个国际组织对卫生技术评估 (Health Technology Assessment, HTA) 进行如下定义和解释：卫生技术评估评价的是各种预防、诊断、治疗疾病、健康促进和康复保健的干预措施，包括药品、生物制剂、医疗器械、卫生材料、医疗方案、操作程序、组织管理系统、后勤支持系统等，其能为各层次的决策者包括政府、医保公司、病人和医生等提供合理选择卫生技术的科学信息和决策依据（O’Rourke et al., 2020）。

（二）价值评估维度

卫生技术评估需要对卫生技术的价值进行评估，而卫生技术具有不同的价值维度，通常包括临床效果、安全性、成本和经济的影响、伦理、社会、文化和法律问题等。

2017 年，国际药物经济学会（International Society for Pharmacoeconomics and Outcomes Research, ISPOR）提出了卫生技术的“价值之花”，涵盖了十三个价值要素，并被广泛认可（Lakdawalla et al., 2018）。随着时代发展，2023 年，美国“不让任何

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* 张田甜：暨南大学南方药物经济学与卫生技术评估研究所

患者掉队 (No Patient Left Behind，NPLB)”组织发布了广义成本效果分析（Generalized Cost-Effectiveness Analysis, GCEA）“价值之花”，该“价值之花”从成本与效果出发，涵盖在四个类别中十五个更广泛的价值要素，为未来卫生技术评估的开展颇有助益（Shafrin et al., 2024）。新旧价值之花的花瓣（即价值要素）映射如表 1 所示。

表 1 GCEA价值花瓣与ISPOR价值花瓣的映射

类别	GCEA	ISPOR
不确定性	结局的不确定性	希望的价值
		减少不确定性
	疾病风险的降低	保险的价值
	知晓的价值	-
动态要素	动态净卫生成本	净成本
	动态患病率	-
	社会折现率	-
	选择的价值	真正的选择价值
	科学的溢出效应	科学的溢出效应
受益者	以患者为中心的健康改善	QALYs 产出
		疾病严重程度
	公平性	公平性
	家庭/照护者的溢出效应	生产力
额外价值要素	社区溢出效应	减少对传染的恐惧
	生产力	生产力
	依从性	依从性改善
	直接非医疗费用	净成本

（三）医疗器械的价值评估维度

医疗器械也是卫生技术的一种，但医疗器械与药物之间不同的特征等因素造成了二者之间的固有差异，比如不同的操作 / 给药方式、临床证据的产生过程、研究的实施和要求，以及不同的产品生命周期等。种种不同这进一步造成了医疗器械与药品等卫生技术的价值维度存在差异，医疗器械的价值维度见表 2。

表 2 医疗器械的价值维度

维度	内容
临床价值	满足临床未满足需求（增加或改进新功能）； 提升安全性（降低风险）； 提升临床效率； 提高诊疗效果； 增加技术提供可及性； 改进产品关键技术参数。
经济价值	减少其他直接/间接医疗费用； 节约配套要求（设备、原材料）费用； 降低诊疗运行维护成本； 治疗费用降低； 医疗服务价格降低； 成本效果（性价比）分析结果更优； 预算影响 。
创新性	国内首仿，局部，过程有研发贡献； 自主研发。在成果问世前，发现国外有同步开发产品，在不可国度获注册证时间差不超过一年； 全球引领，有突破性研发成果。
技术特性	医疗器械的成熟度、人员要求、设备要求、技术维护要求、操作技能等方面。
社会适宜性	使用该医疗器械后可能引起的社会环境变化，包括社会、伦理和法律的变化； 是否会加剧社会健康不平等。

二、手术机器人IDEAL框架

手术机器人是医疗器械的一种，其结合了精密机械、计算机科学和生物医学工程等多个学科的最新成果，是现代医疗领域的一项革命性进步，自20世纪末以来，

手术机器人经历了从初步探索到广泛应用的发展过程。最初的手术机器人系统主要用于辅助医生进行精确的手术操作，而随着技术的进步，如今手术机器人已经能够执行复杂的手术任务，如微创手术和远程手术等。手术机器人的应用能提高手术的精确度和安全性，减少人为操作的误差，并减少患者的创伤和术后并发症，改善患者预后，提高生活质量，缩短患者的恢复时间，同时也为外科医生提供了新的手术工具和方法。

由IDEAL协作网推出的“IDEAL框架与建议”旨在针对新的外科手术、有创性医疗器械和其他复杂治疗干预措施建立科学、严谨的评价路径，并根据干预措施发展所在阶段推荐研究方法、报告规范等实施的关键要素。目前，IDEAL已成为国际公认的外科临床研究方法学范式。2024年，IDEAL协作网发表了适用于手术机器人的IDEAL框架，从设备开发者、临床医生、患者以及更广泛的医疗卫生系统四个视角出发为手术机器人在开发、比较研究和临床监测的三个阶段提出了评估建议（Marcus et al., 2024）。三个阶段分别是，对新设想的手术机器人的安全性和可行性进行早期临床研究的IDEAL阶段 0、1和2a；更大规模上研究机器人干预措施的有效性，并将其与当前最佳实践进行比较的IDEAL 阶段2b 和3；以及当机器人被广泛采用时，将重点转向在现实世界环境中对性能的长期监测的IDEAL阶段4。各阶段各视角具体的建议列于表3。

表格3 手术机器人IDEAL框架各阶段各视角的建议

IDEAL阶段	利益相关者	关键建议
0 (pre-IDEAL) 1（设想） 2a（开发）	设备开发者	在同行评审期刊中标准化发布技术和临床数据。
		透明记录设备、适应症、患者和AI模型的变更。
		AI集成机器人评估应首先分别检查AI方面，然后通过离线和基于模拟的评估来评估集成机器人（IDEAL阶段0）。人体首次研究（IDEAL阶段1）及以后应评估临床背景下的集成机器人，使用临床结果，并遵循报告指南（例如，DECIDE-AI）。
		根据水平和风险评估机器人自主性。
	临床医生	定义、分析并迭代临床医生-设备整合，考虑利益相关者视角、临床医生行为和认知负荷。
		对于自主系统，评估交接机制的可靠性和人类接管的原因。

IDEAL阶段	利益相关者	关键建议
	患者	确保透明同意流程，涉及理论风险、证据、系统故障缓解、自主性水平、手术团队经验和潜在利益冲突。
	卫生系统	进行早期和迭代的经济建模，使用探索性分析，以指导进行具有成本效益的开发，防止未来研究浪费。 考虑外科机器人对不同医疗保健生态系统的影响，尽可能使用生命周期评估、逆向工程和节俭设计概念来提高可及性和可持续性。
2b（探索） 3（评价）	设备开发者	通过前瞻性数据收集评估手术机器人的风险和益处，使用合适的研究设计、共同商定的数据集、适当的分析技术和评估研究特定的混杂因素。 根据风险、自主性水平和可用证据重新评估机器人的其他适应症。
	临床医生	使用验证过的工具和定性研究探索人因因素(人体工程学)。 研究手术机器人在真实世界中的学习曲线，从真实世界和模拟使用案例中收集指标。 建立具有一致规范的机构临床治理政策，涉及外科医生培训、审计和伦理。
	患者	通过评估患者观点、理解和同意来探索机器人手术的可接受性。 向参与者保持透明度，涉及现有证据、发展阶段、利益冲突、手术经验、并发症和替代治疗方案。
	卫生系统	在比较研究中测量与机器人干预相关的医疗卫生成本的经济影响，包括在足够长的随访期间内临床和系统相关结果。 纳入低资源环境中的利益相关者，对机器人使用的能力、益处和风险进行建模，并与现有替代方案进行比较。 将手术机器人的生命周期评估与当前的金标准治疗进行比较。

IDEAL阶段	利益相关者	关键建议
4（长期监测）	设备开发者	长期监测应由真实世界数据（RWD）领导，以提供高质量、透明和有效的数据。 评估手术机器人必须定制化，以适应其动态特性，特别是针对 AI 系统，并检测设备的性能变化。
	临床医生	应使用并由认证机构认可的标准化培训项目，并根据比较阶段的发现进行指导。 应进行外科医生的再验证和认证，以确保机器人手术技能保持高标准。所有不良事件应进行人类和卫生系统因素分析，并由专家进行。
	患者	注册系统和长期监测研究应该能独立获取，且以患者能够理解的格式呈现并随时可用。 长期监测研究应以患者报告的结果测量为主，确保结果保持以患者为中心。
	卫生系统	应进行手术机器人的成本效果分析，并由真实世界数据驱动的决策分析模型提供信息。此外，成本将受到学习曲线、技术错误、系统故障、动态定价和其他因素的影响，意味着真实世界数据，包括健康数据、行政索赔数据和前瞻性观察研究，对于在 IDEAL 阶段 4 中建模机器人辅助手术系统的真实价值至关重要。 国际论坛应评估和减轻由手术机器人引入的全球健康不平等。在长期评估中，必须进行可持续性评估和环境影响评估，并定期与专家利益相关者咨询。

值得注意的是，该手术机器人IDEAL框架在各个阶段都提出经济性评价的要求。在设想和开发阶段，需要进行早期的经济建模和探索性分析，以指导进行具有经济性的开发；而在探索和评价阶段，需要在比较研究中测量与机器人干预相关的医疗卫生成本的经济影响，包括在足够长的随访期间内临床和系统相关结果；最后在长期监测阶段，应进行手术机器人的成本效果分析，并由真实世界数据驱动的决策分析模型提供信息。因此，需要格外注意手术机器人经济性评价中存在的挑战，并采取适当的措施进行应对。例如，Simianu等（2020）构建了一个决策分析模型从社会和医疗卫生体系的角度对开放手术、腹腔镜手术和机器人辅助手术在结肠切除术中的应用进行了成本效果评估，结果表明腹腔镜和机器人辅助结肠切除术比开放切除术更具经济性（Simianu et al.，2020）。

三、手术机器人HTA的注意事项及建议

手术机器人作为卫生技术的一种，同样需要对其进行评估，但手术机器人作为与其他卫生技术别有不同的技术，对其进行卫生技术评估也存在一些事项，需要格外注意，慎重应对，下面将列出一些重要的注意事项并给出相应建议。

（一） 证据纳入和排除

手术机器人的临床研究工作通常开展不多,文献较少,同时因为缺乏适当的对照、随机化和盲法等因素，临床研究中产生的证据质量和水平可能不太可靠，同时这些研究通常规模较小，在评估手术干预措施时普遍性可能有限。因此，可考虑将其他诸如病例报告、队列研究、病例对照研究和真实世界研究等类型的证据纳入，但需注意证据的质量。

（二） 患者与医生视角

如果对手术机器人的卫生技术评估只关注硬性临床结果，可能会忽略可为健康政策决策提供信息的患者益处等因素，或忽视外科医生的人体工程学益处。所以应考虑反映患者和临床医生视角的结果，如患者的偏好和满意度，外科医生在手术过程中的舒适度和工作效率等。

（三） 学习曲线效应

随着实践次数的增加，外科医生执行手术机器人的性能表现会逐渐提高，带来的健康结果也就不同，进一步影响相应的成本，为评估带来不确定性。所以对手术机器人进行卫生技术评估应考虑临床医生能力差异，并在可能的情况下纠正学习曲线效应（Erskine et al., 2023）。这就要求，在选择临床有效性证据时，使用适合自己研究所设置的手术量和手术机器人经验的数据，并分析手术机器人相关临床证据随时间的变化，以观察其性能是否稳定，还应使用敏感性分析来探讨相应性能变化的影响。对于量化学习曲线，可以参考欧洲卫生技术评估网络（EUnet HTA）为分析学习曲线的影响提出的三阶段方法。

（四） 成本分配

手术机器人本身并不能直接发挥作用，需要将其纳入某个或多个手术中。但是，一些卫生技术评估将手术机器人系统的全部资本成本分配到单个手术的手术量中，

可能会导致结果偏差。更合理的方法是将成本分摊到机器人处理的所有手术中，根据手术机器人实际执行的手术数量来计算成本，如此方能更全面地反映医院或卫生系统目前如何使用手术机器人来覆盖各种患者手术。

（五） 分析方法

目前许多手术机器人的经济性评估仅仅考虑了手术机器人相较于传统手术方法的成本，使得其评估结果并不全面，参考价值有限。应使用基于价值的医疗（Value-based Healthcare，VBHC）方法，体现为以相同或更低的成本最大程度地获得最好的临床效果，即追求医疗服务的性价比，而非仅仅比较成本高低。

（六） 合适的时间范围

在评估手术机器人的手术效果时,需要考虑到长期的影响,设置合理的时间范围，包括对患者生活质量和经济成本的长期影响,以及对外科医生福祉的潜在长期影响，这些影响可能不会立即显现，需要长期跟踪和研究才能充分评估。例如，某些临床结果（例如复发）可能在手术后几年才显现，一旦这些临床结果出现，它们对患者的生活质量和经济成本（的影响可能会持续很长时间，甚至可能是终身的。

（七） 组织影响

手术机器人能够为医院整个组织带来一些额外的益处，而这些益处通常不被卫生技术评估所考虑，这些益处包括提高医院运营效率、利于数据分析、远程手术能力等，因此应该考虑整个机器人生态系统的价值。此外，设置手术机器人经常需要大量的组织投资和适应，例如，新的基础设施、多学科团队的创建和监督需求。因此，如果评估手术机器人的成本由卫生服务提供者承担，应在主要分析中包括设置机器人辅助手术平台成本和为优化机器人平台使用而花费（如培训）的成本等，并在敏感性分析中评估这部分费用的影响（Lai et al.，2024）。更进一步，还需要考虑可能被机器人辅助手术替代的开放手术和腔镜手术的比例。

（九） 增量创新

手术机器人设备及其技术会不断被创新，尤其是那些集成了AI的手术机器人，随着新型号或新产品的推出，会影响到临床效果和成本，导致卫生技术评估很快过时，或导致在对其进行评估的研究过程中研究就已经失效（Marcus et al.，2024）。为了应对这些问题，可以采用创新、迭代的评估策略，如实施试验（implementation trials）（Wolfenden et al.，2021）。此外，贝叶斯法（Bayesian approach）这种基于先验知识然后不断整合新信息的模型也更为适用（明坚等，2021）。

四、结语

手术机器人作为医疗器械领域的一项前沿技术，其卫生技术评估（HTA）对于确保其在医疗实践中的合理应用和资源的有效配置至关重要。然而，手术机器人HTA的复杂性要求我们在评估过程中必须综合考虑多方面的因素，需特别关注证据的质量与适用性，充分考虑患者和医生的视角，以及学习曲线、成本分配、分析方法、时间范围、组织影响和增量创新等因素，以克服评估过程中的挑战，提高评估结果的准确性和可靠性。总之，手术机器人的HTA是一个复杂而系统的过程，需要综合运用多学科知识和方法，不断探索和创新评估策略。未来，随着技术的持续进步和医疗环境的演变，手术机器人的HTA方法应与时俱进，以更好地服务于医疗决策，促进手术机器人技术的发展，最终实现提高医疗质量和患者福祉的目标。

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北京大学全球健康发展研究院
地址:北京市海淀区颐和园路5号100871
邮箱:ghd@pku.edu.cn
电话:+86 10 6275 7318
网址:www.ghd.pku.edu.cn

PKU Institute for Global Health and Development
5 Yiheyuan Road, Haidian District Beijing, China,100871
E-mail: ghd@pku.edu.cn
Office : +86 10 6275 7318
Website: www.ghd.pku.edu.cn