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Robot-Assisted Surgery For Kidney Cancer Increased Access To A Procedure That Can Reduce Mortality And Renal Failure

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ABSTRACT Surgeons increasingly use robot-assisted minimally invasive surgery for a variety of medical conditions. For hospitals, the acquisition and maintenance of a robot requires a significant investment, but financial returns are not linked to any improvement in long-term patient outcomes in the current reimbursement environment. Kidney cancer provides a useful case study for evaluating the long-term value that this innovation can provide. Kidney cancer is generally treated through partial or radical nephrectomy, with evidence favoring the former procedure for appropriate patients. We found that robot-assisted surgery increased access to partial nephrectomy and that partial nephrectomy reduced mortality and renal failure. The value of the benefits of robot-assisted minimally invasive surgery to patients, in terms of quality-adjusted life-years gained, outweighed the health care and surgical costs to patients and payers by a ratio of five to one. In addition, we found no evidence that the availability of robot-assisted minimally invasive surgery increased the likelihood that inappropriate patients received partial nephrectomy.

The da Vinci Surgical System (manufactured by Intuitive Surgical) was introduced in 2000. Since then, the use of robot-assisted minimally invasive surgery has increased in the United States and internationally. The da Vinci system is the only robotic surgical system cleared by the Food and Drug Administration for general laparoscopic surgery. At the start of 2014 there were 2,083 da Vinci robot-assisted surgery systems installed in the United States and 883 elsewhere in the world, compared with 1,571 total systems in 2010 and 656 in 2007.¹⁻³

In robot-assisted minimally invasive surgery, surgical instruments with a high range of motion and a high-definition camera are introduced into the surgical site through small incisions. Surgeons perform the surgery from a console, where they receive magnified, high-resolution, three-dimensional images of the surgical site.⁴

Ever since the adoption of robotic surgery, significant debate has arisen over its value. Robot-assisted minimally invasive surgery has been shown to reduce complications and lengths-of-stay in some cases⁵⁻⁹ but not in others.^{6,9,10} Robot-assisted minimally invasive surgery is generally reimbursed at the same rates as comparable conventional surgical procedures. However, the costs of acquiring and maintaining a robotic system are significant.¹¹ In 2010 a robot-assisted surgery system cost \$1.0–\$2.3 million to acquire and \$100,000–\$170,000 annually to maintain.^{2,12}

Some observers have questioned whether the up-front investment may increase overall procedure costs and lead hospitals to increase charges to payers.^{11,13-15} There has also been concern that the availability of surgical robots encourages providers to perform procedures on inappropriate patients.¹¹

In evaluations of the value of robotic surgery, costs are typically viewed in the short term—often less than one year—and data limitations have constrained researchers to focus mainly on short-term outcomes.^{5,7,10,16} However, surgical costs are incurred early, whereas improvements in health and longevity can accrue over a lifetime.

Kidney cancer provides a useful case study to explore the diffusion and value of robot-assisted minimally invasive surgery. This is because kidney cancer is prevalent, robots are increasingly being used for its surgical treatment, and excellent data on long-term costs and benefits are available. In 2012 there were 58,222 incident cases of kidney cancer in the United States, which affected 14.84 per 100,000 adults.^{17,18}

Kidney cancer is generally treated with surgery: either partial nephrectomy, in which diseased tissue is removed and healthy tissue is left, or radical nephrectomy, in which the entire kidney is removed. Radical nephrectomy has historically been more common, and some observers have questioned whether partial nephrectomy leads to better outcomes.¹⁹ However, a consensus is emerging that partial nephrectomy is superior for appropriate patients.^{12,20–22}

During the past decade there has been a dramatic increase in the availability of robot-assisted minimally invasive surgery systems to treat kidney cancer.^{1–3} This provides a basis for determining the costs and benefits of robot-assisted surgery systems in nephrectomies for kidney cancer.

Study Data And Methods

We used national cancer registry data linked with Medicare claims for 1995–2010, the period in which robot-assisted minimally invasive surgery became adopted into clinical practice. Because partial nephrectomy is considered the standard of care for clinically appropriate patients,²³ we first compared outcomes of patients receiving partial versus radical nephrectomy. We then analyzed whether robot-assisted surgery expanded access to partial nephrectomy and, if so, whether it expanded access for inappropriate patients.

DATA Patient cost and outcome data were derived from the Surveillance, Epidemiology, and End Results (SEER) Program, linked to Medicare claims. SEER collects cancer incidence and survival information from registries covering 28 percent of the US population.²⁴ SEER-Medicare data are widely used to study clinical and health economic outcomes among cancer patients.²⁵ Our analysis did not extend beyond 2010, because more recent SEER-Medicare data were not available. Sales data containing the

names and locations of hospitals that acquired the da Vinci Surgical System were provided by the manufacturer for 2000–10, by month.

STUDY COHORTS The study sample included Medicare beneficiaries ages sixty-five and older who were diagnosed with kidney cancer between 1996 and 2010 and had a nephrectomy. We required the beneficiaries to be continuously enrolled in fee-for-service Medicare for at least twelve months before and six months after the cancer diagnosis, or until death.

We constructed two cohorts based on the size of the patient's primary renal tumor: for the main analyses, a 7-cm cohort, which included patients whose tumor size was up to 7 centimeters; for a sensitivity analysis, a 4-cm cohort. These definitions are aligned with guidelines from the American Urological Association, which recommend partial nephrectomy for patients in the 4-cm cohort and consideration of partial nephrectomy for patients in the 7-cm cohort.²³

MEASURES To trace the longitudinal effects of surgery, we defined four study periods for each patient relative to the nephrectomy date (which was day 0). The first period was baseline, or days –380 to –15. The second period, perioperative, was days –14 to +28; the third, postoperative, days +29 to +365; and the fourth, long term, was day +366 and after.

Outcomes were one-year survival; renal failure in the perioperative, postoperative, and long-term periods; and “net benefit,” a measure of the value of patient health benefits net of health care costs. To assess net benefit, we first measured the number of quality-adjusted life-years (QALYs) that each patient survived following nephrectomy.

Quality of life was based on the degree of renal insufficiency each year, using literature-based utilities—that is, a measure of quality of life that ranges from 0 for death to 1 for perfect health.²⁶ We used a value of \$150,000 per QALY.^{27–29} From this value we subtracted patient and plan payments for all Medicare-covered costs (except prescription drugs, because of a lack of data). This provided a value of the patient's quality-adjusted survival net of the cost to attain it.

For those patients whose outcomes were observed for at least five years, we measured net benefit during the years after nephrectomy. (Patients were not removed from the analysis if they lacked five years of data because of their death.) For one-year outcomes such as survival and renal failure, we required that patients had been observed for at least one year. We adjusted monetary values to 2010 dollars using the Consumer Price Index.³⁰

Explanatory variables included patient-level

indicators for partial versus radical nephrectomy and a binary variable that indicated the availability of robot-assisted minimally invasive surgery in the patient's hospital referral region (HRR)—the geographic unit in which a given patient was likely to receive care. Because an *International Classification of Diseases*, Ninth Revision (ICD-9), code to track robot-assisted surgery was not introduced until late 2008, and its use was optional, we needed to measure robot-assisted surgery capabilities at the HRR level instead of the patient level.³¹

Covariates were measured in the baseline period. They included the patient's age, sex, race and ethnicity, and marital status; tumor size, grade, and histology; and Charlson Comorbidity Index.³²

We controlled for patients' income, poverty, and education using average characteristics in their ZIP codes from census data. We included indicator variables for three time periods to account for secular changes in outcomes. In analyses in which robot-assisted minimally invasive surgery was the key explanatory variable, we also included previous rates of laparoscopic surgery as a covariate.

MAIN ANALYSIS Selection bias is a concern in estimating the effects of partial nephrectomy. For example, a provider's decision to perform partial nephrectomy may be influenced by unobserved factors such as the patient's underlying health or the provider's skill, both of which may be correlated with outcomes. We addressed potential selection bias by performing our analyses at the HRR level, using a difference-in-differences approach. Patients within an HRR may differ in their health and socioeconomic status. However, such differences will generally be smaller over time within HRRs than across HRRs.³³

We examined the effects of changing partial nephrectomy rates within HRRs by aggregating our data to the HRR-year level.³⁴ We used multivariable linear regression analysis to estimate the effect of the partial nephrectomy rate in an HRR-year on rates of one-year survival; perioperative, postoperative, and long-term renal failure; and average five-year net benefit from nephrectomies in the HRR in a given year. Covariates were demographic and clinical characteristics of patients in the HRR-year, a series of indicators for time periods, and HRR-level fixed effects to control for time-invariant characteristics of HRRs.

We applied standard techniques for modeling costs by computing the natural logarithm of the average transformed net benefit. This served as the outcome variable for linear regression analysis. Results were then transformed from logs to

dollars using Duan's smearing estimator.³⁵

Next we estimated the effect of the availability of robot-assisted surgery in a given HRR-year on the rate of partial nephrectomy. Specifically, we estimated a difference-in-differences linear model in which the outcome variable was the rate of partial nephrectomy and the main explanatory variable was the presence of robot-assisted surgery in an HRR-year. The model included the same covariates as in the above analyses, with the addition of controls for previous rates of laparoscopic surgery.

American Urological Association guidelines state that partial nephrectomy might not be appropriate for all patients.²³ To test whether robot-assisted surgery expanded access to partial nephrectomy among inappropriate patients, we measured the appropriateness of patients for partial nephrectomy and investigated whether partial nephrectomy patients in areas with robot-assisted surgery capabilities were less appropriate than partial nephrectomy patients in other areas. To do this, we used previously validated methods to calculate an appropriateness index for patients and then examined whether the typical patient receiving partial nephrectomy in areas with a robot was less appropriate than the typical patient receiving the procedure in other areas (which would be consistent with robots' allowing providers to expand the number of patients receiving care).^{36,37}

Details of our methodology are available in the online Appendix.³⁸

SENSITIVITY ANALYSES We conducted sensitivity analyses. First, we estimated models with year rather than period fixed effects. Second, we estimated models excluding HRR fixed effects. Third, we explored whether HRRs that had relatively larger increases in robot-assisted procedures over time also had greater increases in the proportion of patients with partial nephrectomies. This analysis assessed the existence of a "dose-response" relationship between the overall intensity of robot use in an area and the likelihood of having a partial nephrectomy performed. Finally, we estimated the net benefit of partial nephrectomy in the 4-cm cohort.

LIMITATIONS Our study had several limitations. First, we focused on kidney cancer, and our results might not be generalizable to other cancers.

Second, our data were restricted to Medicare. Robot-assisted surgery may produce greater benefits in working-age adults because of their longer time horizon for health gains to accrue.

Third, minimally invasive surgery may lead to lower complications and therefore higher quality of life. This would make our estimates conservative.^{39,40}

Fourth, several novel therapies to treat kidney cancer (sorafenib, pazopanib, and sunitinib) were introduced after 2006. If these were disproportionately prescribed in HRRs that adopted robots, our survival analyses could be confounded. However, our analyses of renal failure should be unaffected, since these therapies do not influence the likelihood of renal failure.

Fifth, our estimates of the effect of robot introduction in an HRR on partial nephrectomy rates may be confounded. We used a difference-in-differences approach that accounted for time-invariant factors in an HRR that influenced partial nephrectomy rates. However, it is still possible that HRRs that adopted robots could have had higher future partial nephrectomy rates even if they had not adopted robots.

Study Results

COHORTS We studied 17,039 patients in the 7-cm cohort and 9,750 patients in the 4-cm cohort. In the 7-cm cohort, there were 3,112 partial (18.3 percent) and 13,927 radical nephrectomies (81.7 percent). In the 4-cm cohort, the share of partial nephrectomies was higher (27.0 percent). For additional descriptive statistics, see the online Appendix.³⁸

Compared to radical nephrectomy patients, partial nephrectomy patients were younger (73.2 versus 74.7 years), were more likely to be male (61.1 percent versus 56.6 percent), and

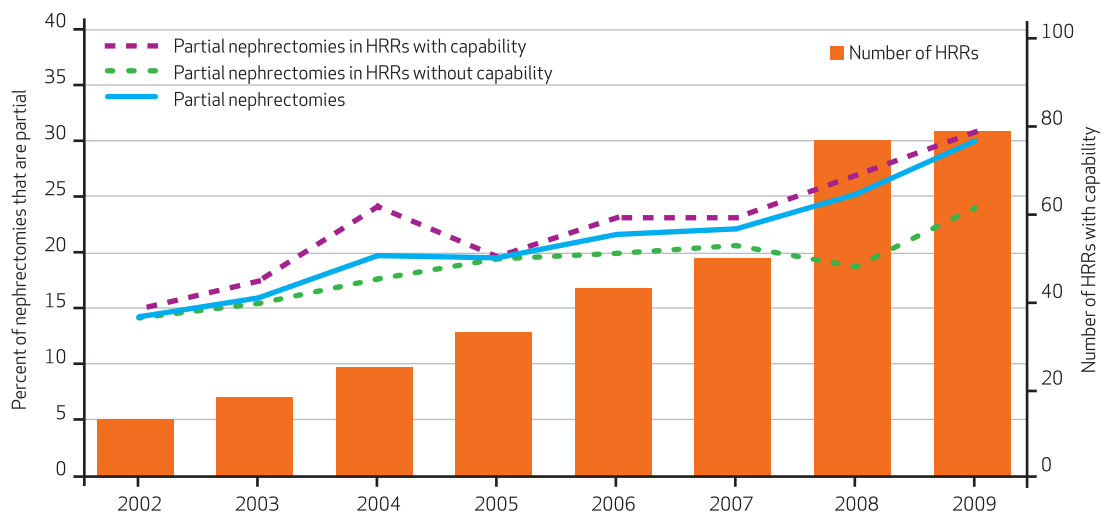
lived in areas with higher median incomes (\$54,162 versus \$50,735). On average, partial nephrectomy patients had smaller tumors that were more likely to be localized.

Access to robot-assisted minimally invasive surgery increased during the study period (Exhibit 1). Of the 187 HRRs represented in the data, 13 (7.0 percent) had the capability to perform robot-assisted surgery in 2002, compared to 79 (42.2 percent) in 2009. The rate of partial nephrectomy among patients in the 7-cm cohort climbed from 14.2 percent in 2002 to 30 percent in 2009. The composition of the group of HRRs with robot-assisted surgery capability changed as more HRRs adopted the robot. However, the rate of partial nephrectomy was consistently higher among HRRs with robot-assisted capability than among those without it. In 2009 one-quarter of the HRRs in our study performed no partial nephrectomies.

EFFECTS OF PARTIAL NEPHRECTOMY We found that the HRRs most likely to offer a partial nephrectomy attained significantly better survival rates than HRRs offering partial nephrectomy at lower rates (Exhibit 2). In particular, an increase in partial nephrectomy rates within a given HRR from the 25th percentile (a 0 percent partial nephrectomy rate) to the 75th percentile (25 percent partial nephrectomy rate) was associated with a 2.2 percent increase in one-year survival among nephrectomy patients, from 89 percent to 91 percent. This is equivalent to an 18 percent

EXHIBIT 1

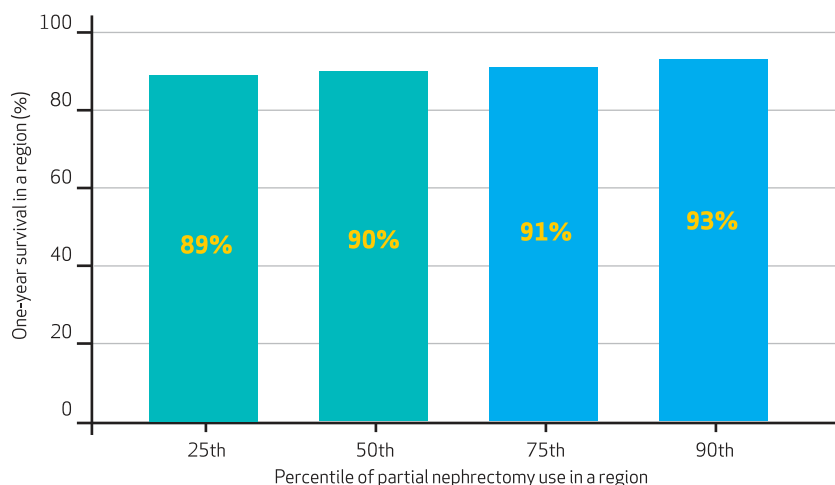
Rates Of Partial Nephrectomy In Patients With Renal Tumors Up To 7 cm And Number Of Hospital Referral Regions With The Capability For Robot-Assisted Minimally Invasive Surgery, 2002-09



SOURCE Authors' analysis of SEER-Medicare data (see Note 25 in text) and Intuitive Surgical sales data. **NOTES** The SEER-Medicare data included 187 hospital referral regions (HRRs). Partial nephrectomies (percentages) are denoted by the line graph and relate to the left-hand y axis. Number of HRRs with the capability for robot-assisted minimally invasive surgery is denoted by the bar graph and relates to the right-hand y axis.

EXHIBIT 2

One-Year Survival Rate At Various Rates (Percentiles) Of Partial Nephrectomy



SOURCE Authors' analysis of SEER-Medicare data (see Note 25 in text). **NOTES** The positive effect of partial nephrectomy on survival was significant ($p < 0.01$). The partial nephrectomy rates at the 25th, 50th, 75th, and 90th percentiles were 0 percent, 12 percent, 25 percent, and 40 percent, respectively. Results are for the 7-cm cohort. The analysis was on the hospital referral region (HRR)-year level, and a panel fixed-effect model was used. Covariates were the fraction of nephrectomies that were partial; year category; and patients' mean age, tumor size, tumor grade, histology, race, sex, marital status, mean baseline Charlson Comorbidity Index, median income, fraction of residents of patients' ZIP codes living below the federal poverty level, and average education level in patients' ZIP codes.

reduction in one-year mortality.

HRRs most likely to offer partial nephrectomy attained significantly lower rates of renal failure in all three time periods (Exhibit 3). If a given HRR were to raise its partial nephrectomy rate from the 25th to the 75th percentile, its rate of renal failure would fall from 20 percent to 15 per-

cent in the perioperative period (a 25 percent decline), from 27 percent to 22 percent in the postoperative period (a 19 percent decline), and from 49 percent to 44 percent in the long-term period (a 10 percent decline).

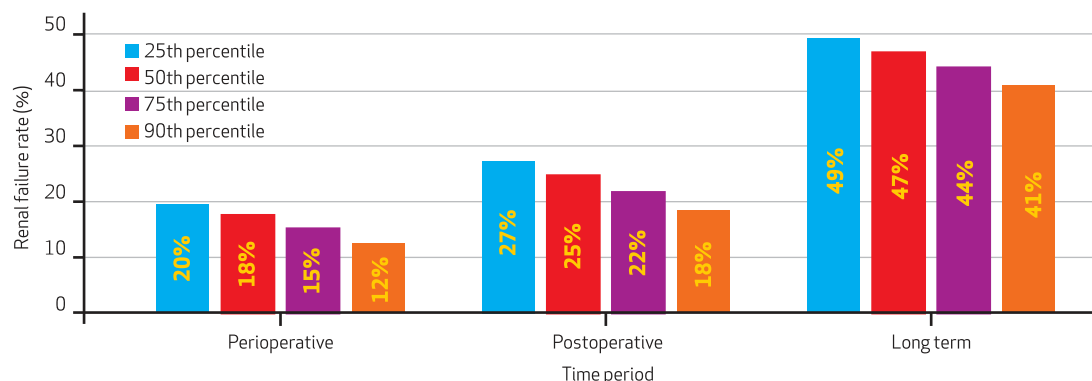
In the five years following surgery, both partial and radical nephrectomy patients experienced more value through improvements in quality-adjusted survival than the health care costs incurred, including the costs of nephrectomy itself (for additional detail on this analysis, see the Appendix).³⁸ Specifically, the five-year net benefit was \$406,217 for radical and \$512,561 for partial nephrectomy patients, for a difference between the two groups of \$106,344. This difference indicates that partial nephrectomy was cost-effective, since it increased quality-adjusted survival compared to radical nephrectomy (through higher survival and lower renal impairment rates), which outweighed the costs incurred to attain those outcomes.

EFFECT OF ROBOT-ASSISTED SURGERY ON RATES OF PARTIAL NEPHRECTOMY

Next we investigated whether the dissemination of robot-assisted minimally invasive surgery expanded access to partial nephrectomy. We found that the adoption of such surgery in an HRR led to a 52 percent increase in the rate of partial nephrectomy (Exhibit 4). To describe the magnitude of this effect, we multiplied the 7.8-percent-age-point increase by the estimated 297,000 nephrectomies performed in the United States in 2001-10. This produced an estimate of the extent to which partial nephrectomy rates would have increased had all HRRs acquired robot-assisted minimally invasive surgery capability,

EXHIBIT 3

Rate Of Renal Failure At Various Rates (Percentiles) Of Partial Nephrectomy



SOURCE Authors' analysis of SEER-Medicare data (see Note 25 in text). **NOTES** The negative effects of partial nephrectomy on renal failure were significant in all three time periods, which are explained in the text ($p < 0.01$). The partial nephrectomy rates at the 25th, 50th, 75th, and 90th percentiles were 0 percent, 12 percent, 25 percent, and 40 percent, respectively. Results are for the 7-cm cohort. The analysis was on the hospital referral region (HRR)-year level, and a panel fixed-effect model was used. For covariates, see the Notes to Exhibit 2. Rates of renal failure were measured including only patients who were alive in the given time period.

compared to no HRR having the capability. We found that if all HRRs had adopted the robot, there would have been an additional 23,166 partial nephrectomies. Valuing each procedure at \$106,344 (as above) would imply a total value of \$2.5 billion.

APPROPRIATENESS OF PATIENTS FOR PARTIAL NEPHRECTOMY We measured the appropriateness of patients for partial nephrectomy and tested whether patients undergoing the procedure in areas that had robot-assisted capability were less appropriate than patients undergoing it elsewhere (for additional detail on this analysis, see the Appendix).³⁸ We found that the availability of robot-assisted surgery was not a significant predictor of patient appropriateness. In other words, we did not find that patients receiving partial nephrectomy in areas where robot-assisted surgery had been adopted were any less appropriate for the procedure than patients receiving it elsewhere (see the Appendix for additional details).³⁸

OTHER EFFECTS Our findings were qualitatively similar across sensitivity analyses, such as when we included year fixed effects or excluded HRR fixed effects (additional detail on these analyses, see the Appendix).³⁸ HRRs with greater growth in the number of robot-assisted procedures also experienced greater growth in the percentage of nephrectomies that were partial. This suggests a dose-response relationship between overall intensity of robot use in an HRR and the likelihood of partial nephrectomy. Finally, we found that the net benefit was similar in the 4-cm cohort compared to the 7-cm cohort.

Discussion

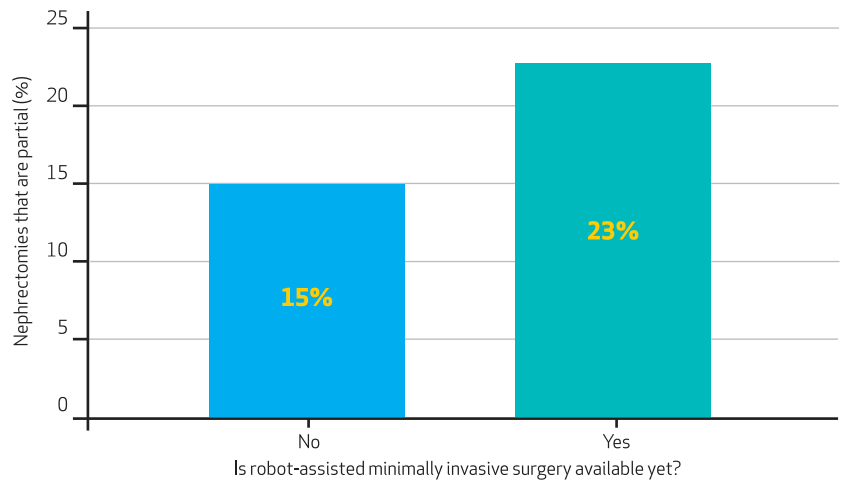
We found that for appropriate patients, partial nephrectomy led to improved kidney cancer outcomes, compared to radical nephrectomy. We also found that use of robot-assisted surgery might increase access to partial nephrectomy. Increasing partial nephrectomy rates was associated with improvements in one-year survival rates after surgery and large reductions in renal failure rates.

Our findings are consistent with those of previous studies.^{20,41-44} For example, we found that partial nephrectomy improved one-year mortality by 5.7 percentage points. In comparison, Hung-Jui Tan and colleagues found a 5.6-percentage-point improvement in two-year mortality.²⁰

Partial nephrectomy has also been found to slow the progression to renal failure.⁴¹⁻⁴⁴ No study has measured the net economic benefit of partial nephrectomy, but several studies have estimated costs similar to ours.⁴⁵⁻⁴⁷ Finally, other

EXHIBIT 4

Rates Of Partial Nephrectomy In A Hospital Referral Region (HRR) Before And After The Adoption Of Robot-Assisted Minimally Invasive Surgery (MIS)



SOURCE Authors' analysis of SEER-Medicare data (see Note 25 in text) and Intuitive Surgical sales data. **NOTES** The difference between whether or not robot-assisted MIS was available was significant ($p < 0.05$). The analysis was on the HRR-year level, and a panel fixed-effects model was used. For covariates, see the Notes to Exhibit 2. Additionally, the rate of laparoscopic surgery in the previous year was included as a covariate. The estimation of the number of nephrectomies during 2001-10 was based on (1) the authors' analysis of data from the Medicare Limited Data Set Files and (2) Porter MP, Lin DW. Trends in renal cancer surgery and patient provider characteristics associated with partial nephrectomy in the United States (see Note 49 in text).

studies have found that robot-assisted surgery expands access to partial nephrectomy and may enable patients with complex tumors to receive partial nephrectomies.^{48,49}

Given the potential benefits to patients of partial nephrectomy, the question becomes how access to the procedure can be expanded. This issue is particularly salient since one-quarter of the HRRs in our study performed no partial nephrectomies in 2009.

There is clearly room for increasing partial nephrectomy rates, and our study identifies one possible route of improvement. We found that the availability of robot-assisted surgery increased the rate of partial nephrectomy in an HRR by 52 percent. Moreover, we found no evidence that patients who received partial nephrectomy in HRRs that had adopted the robot were less appropriate than patients who received the procedure in nonadopting HRRs.

Given debates over the use of robot-assisted surgery for nephrectomies, hysterectomies, prostatectomies, and other minimally invasive surgeries, it is critical to understand not only the clinical benefits of expanding access to robot-assisted surgery but also the economic effects of robot diffusion. Using 2010 data on the acquisition and maintenance costs of the da Vinci Surgical System and on the intensity of its use in nephrectomy in each HRR,^{12,50} and

assuming a five-year life for the equipment,⁵¹ we estimated an annual cost of \$113,000 per HRR to acquire and maintain a robot-assisted system for kidney cancer.

Multiplying the net benefit that we found (\$106,344) by the estimated number of partial nephrectomies that occurred given the availability of robot-assisted surgery (6.17 per HRR per year) yielded a net benefit of \$656,000 per HRR per year. Adding a robotic system to an HRR therefore would yield \$543,000 per year in benefits for kidney cancer patients beyond the system's costs. This calculation ignores the benefits and costs associated with other conditions in which robot-assisted minimally invasive surgery could be used, such as hysterectomies and prostatectomies. Future work should quantify the economic value of such other robot-assisted procedures.

Our simplified analysis yielded a benefit-to-cost ratio of more than 5 to 1. This is a conservative estimate for several reasons. First, we used the highest possible acquisition and maintenance costs. Second, we allowed benefits to accrue for only five years, instead of a longer period. Third, patient benefits were net of the costs paid by the insurer and out-of-pocket costs paid by the patient—some of which money the hospital would likely have used to cover the costs of the robot-assisted surgery system. Fourth, the calculation ignored potential future improvements in life expectancy.

Our analysis highlights the importance of understanding how the costs and benefits of robot-assisted surgery accrue over time. Hospitals bear the short-term costs of acquiring robotic systems. In contrast, the longer-term benefits of improved health accrue to patients, and the reduced costs of avoided complications accrue to

both patients and payers.

This raises the question of whether different payment models provide different incentives to adopt robot-assisted surgery systems. Standard fee-for-service systems, which reimburse only for procedures that were performed, would not capture the benefit stream. However, a longer-term bundled payment system would do so.

The fact that integrated delivery systems such as Geisinger (which provides care to patients covered by Geisinger's health plan) have adopted robot-assisted surgery systems, even when they were not specifically paid to do so, suggests that this approach may offer added value for patients and providers. It is also a widely shared belief that payment systems should reward providers for health, not health care. Robot-assisted surgery use may proliferate more rapidly under such value-based payment models.

Conclusion

Our study suggests that partial nephrectomy delivers sizable benefits to patients with kidney cancer. It also suggests that robot-assisted surgery may increase rates of partial nephrectomy among appropriate patients, without increasing inappropriate use of the procedure.

The value of robot-assisted surgery accrues over a long time, whereas the costs are up front. This implies that short-term analyses could mistakenly conclude that the costs of the technology outweigh its benefits.

Finally, our approach to quantifying the long-term benefits of robot-assisted surgery and assessing its appropriate use could be useful in assessing the value of other robot-assisted systems in other applications. ■

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