

# Radical Prostatectomy Innovation and Outcomes at Military and Civilian Institutions

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The rapid pace of clinical innovation—including the development of novel drugs, devices, diagnostic techniques, and surgical interventions—makes the practice of medicine in the United States dynamic. Hospitals and physicians constantly seek to offer new technologies that are effective and help speed recovery, thereby achieving the best possible results for patients. One example of clinical innovation is minimally invasive surgery (MIS), which is associated with fewer complications across a range of procedures.<sup>1</sup> Recently, the introduction of robotic surgery has made MIS feasible for even complex surgical procedures such as radical prostatectomy (RP) for the management of prostate cancer in hopes of reducing its well-recognized surgical morbidity.<sup>2-4</sup> Minimally invasive RP (MIRP) with laparoscopy was first reported in 1997<sup>5</sup> and robotic MIRP with the da Vinci Surgical System (Intuitive Surgical, Inc; Sunnyvale, California) was introduced in 2001.<sup>6,7</sup> MIRP has become the most common treatment for men with prostate cancer,<sup>8,9</sup> with the latest 2013 estimates showing 85% of all RPs were performed using the robotic approach, with the remainder still being performed via the open radical prostatectomy (ORP) approach.<sup>10</sup>

Prior investigations report that the widespread dissemination of clinical innovation, such as MIRP, in the United States has been associated with patient, surgeon, and hospital characteristics.<sup>11-13</sup> These studies, however, did not directly examine the question of how the funding mechanism for healthcare services may have altered this adoption. In theory, hospitals that rely on revenue through reimbursement of services (ie, for-profit and nonprofit institutions) will preferentially adopt new clinical innovations at a faster rate because they attract patients, thereby maximizing hospital revenue.<sup>14</sup>

In the current study, we analyzed a contemporary cohort of male enrollees in TRICARE, the healthcare program of the United States Department of Defense (DoD) Military Health System (MHS). These men all have prostate cancer and underwent RP at either civilian hospitals or military hospitals, which have substantially different models for healthcare delivery. We compared cohorts from

## ABSTRACT

**OBJECTIVES:** Limited data are available regarding the impact of the type of healthcare delivery system on technology diffusion and associated clinical outcomes. We assessed the adoption of minimally invasive radical prostatectomy (MIRP), a recent clinical innovation, and whether this adoption altered surgical morbidity for prostate cancer surgery.

**STUDY DESIGN:** Retrospective review of administrative data from TRICARE, the healthcare program of the United States Military Health System. Surgery occurred at military hospitals, supported by federal appropriations, or civilian hospitals, supported by hospital revenue.

**METHODS:** We evaluated TRICARE beneficiaries with prostate cancer (*International Classification of Disease, 9th Revision, Clinical Modification* [ICD-9-CM] code: 185) who received a radical prostatectomy (60.5) between 2005 and 2009. MIRP was identified based on minimally invasive surgery codes (54.21, 17.42). We assessed yearly MIRP utilization, 30-day postoperative complications (Clavien classification system), length of stay, blood transfusion, and long-term urinary incontinence and erectile dysfunction.

**RESULTS:** A total of 3366 men underwent radical prostatectomy at military hospitals compared with 1716 at civilian hospitals, with minimal clinic-demographic differences. MIRP adoption was 30% greater at civilian hospitals. There were fewer blood transfusions (odds ratio, 0.44;  $P < .0001$ ) and shorter lengths of stay (incidence risk ratio, 0.85;  $P < .0001$ ) among civilian hospitals, while 30-day postoperative complications, as well as long-term urinary incontinence and erectile dysfunction rates, were comparable.

**CONCLUSIONS:** Compared with military hospitals, civilian hospitals had a greater MIRP adoption during this timeframe, but had comparable surgical morbidity.

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these disparate healthcare environments to evaluate the hypothesis that civilian hospitals preferentially adopted MIRP compared with MHS hospitals, resulting in an improved surgical morbidity profile for patients with prostate cancer.

## METHODS

### Data

TRICARE is the healthcare program serving active-duty and retired service members and their dependents. This program provides 3 types of health plans: Standard (similar to traditional indemnity insurance), Extra (similar to a preferred provider organization), and Prime (similar to a health maintenance organization). Prime enrollees have a primary care manager (PCM) responsible for their care. TRICARE Plus provides enrollees 65 years or older with access to MHS facilities and benefits comparable to Prime, where available. Services provided by TRICARE are via the Direct Care System at MHS facilities where healthcare professionals are salaried, either as employees of the federal government or as hired contractors. There is also a Purchased Care System (PCS), which reimburses for services at civilian facilities, comprising for-profit and nonprofit institutions in which hospitals and surgeons maximize revenue by increasing the volume of care (ie, fee-for-service).<sup>15</sup> Although all active-duty service members typically receive care at military treatment facilities, some TRICARE enrollees (eg, retirees or family members) may also receive care in the PCS, depending on where they reside.

We extracted data from October 1, 2005, to September 30, 2010, from the Military Health System Data Repository (MDR), an administrative database, for all TRICARE Prime and Plus beneficiaries within the United States. We focused on Prime and Plus beneficiaries for 2 reasons. First, the assignment of a PCM who oversees care suggests it is less likely that enrollees might receive care that is not performed within the purview of TRICARE and that care provided might be documented more completely. Second, although all TRICARE benefit plans are generous, Prime enrollees have either very low or no enrollment fees and co-payments, and no deductibles, minimizing the possibility that patient out-of-pocket costs might be a factor in treatment selection. We obtained approval from the institutional review boards of the Uniformed Services University of the Health Sciences and Brigham and Women's Hospital and established a data use agreement with the Defense Health Agency Privacy Office.

### Study Cohort and Outcomes

We identified 28,998 men with a diagnosis of prostate cancer (*International Classification of Disease, 9th Revision, Clinical*

## TAKEAWAY POINTS

This is a retrospective review of administrative data from TRICARE, the healthcare program of the United States Military Health System.

- ▶ Compared with 1716 men in 767 civilian hospitals, 3366 men underwent radical prostatectomy in 36 military hospitals.
- ▶ Minimally invasive radical prostatectomy adoption was 30% greater at civilian hospitals.
- ▶ The 30-day postoperative complications, as well as long-term urinary incontinence and erectile dysfunction rates, were comparable.
- ▶ Adoption of minimally invasive technology has not significantly improved surgical morbidity.
- ▶ This study suggests that adoption of technology may not always translate to an observable improvement in patient outcomes.

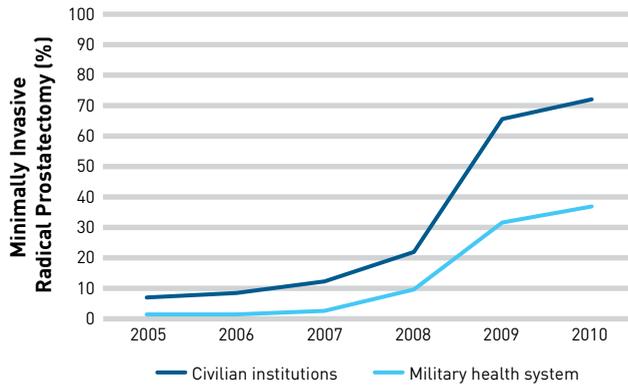
*Modification [ICD-9-CM] code: 185*). Of these, 5082 underwent RP (*ICD-9-CM: 60.5*). We examined outcomes describing RP morbidity, including surgical complications and blood transfusions, length of stay (LOS), anastomotic strictures, postoperative incontinence, postoperative erectile dysfunction, and the postoperative complication rates during the 30 days following surgery. Thirty-day surgical complications were determined based on the Clavien classification system, a validated approach for reporting complications<sup>16</sup> using *ICD-9-CM* codes as described previously.<sup>17</sup> We evaluated for any complication (Clavien grade  $\geq 1$ ), major complications (Clavien grades 3-5), and mortality (Clavien grade 5). Postoperative mortality was identified through disposition codes in the MDR. Postoperative blood transfusions were also assessed in the 30 days after surgery through a review of the administrative data.

LOS was calculated based on the days between the surgery and discharge from the hospital. The development of anastomotic strictures (*ICD-9-CM: 598.2, 598.8, 598.9*) was captured from 31 to 365 days after surgery, thus limiting the years of analysis from fiscal year (FY) 2005 to FY 2009. Long-term functional status was estimated based on the use of surgical procedures to address incontinence and erectile dysfunction during the 18 months following surgery, thus excluding men undergoing surgery in the latter half of FY 2009 and in FY 2010. The codes used to capture incontinence and erectile dysfunction have been previously described.<sup>11</sup>

### Covariates

We extracted demographic information pertinent to our study cohort, including patient age, race, and marital status, as well as clinical information, such as baseline incontinence and erectile dysfunction. For missing data, efforts were made to cross-reference multiple datasets to obtain accurate demographic information. We dichotomized the surgical approach as ORP (*ICD-9-CM: 60.5* only) or MIRP (*ICD-9-CM: 60.5 + 54.21 and/or 17.42*). To adjust for patient health status, we utilized the CMS-Hierarchical Condition Category (CMS-HCC) model, which uses demographics and diagnosis profiles captured for both inpatient and ambulatory encounters in order to adjust capitation payments for health expenditure risk.<sup>18</sup> We used CMS-HCC both as a continuous and a categorical variable (tertiles).

**FIGURE.** Rates of Minimally Invasive Radical Prostatectomy Among TRICARE Beneficiaries, in Civilian Institutions and in the Military Health System (2005-2010)



**TABLE 1.** Clinical, Demographic, and Surgical Characteristics of the Study Population, Stratified by Healthcare System

Number of patients	Military Institutions n = 1716	Civilian Institutions n = 3366	P
<b>Age, years</b>			
Mean ± SD	58.5 ± 8.0	58.5 ± 7.0	.9
<b>Race</b>			
White	64.6%	57.3%	<.0001
Black	24.9%	19.9%	
Asian/Native American/other	10.4%	4.2%	
Unknown/missing	0.1%	18.5%	
<b>Marital status</b>			
Married	84.5%	84.7%	.0005
Single	9.6%	11.1%	
Unknown	5.9%	4.2%	
<b>CMS-HCC</b>			
Median (IQR)	0.38 (0.24)	0.36 (0.20)	.3
<b>Surgical approach</b>			
Open	86.9%	66.4%	<.0001
Minimally invasive	13.1%	33.6%	

CMS-HCC indicates CMS-Hierarchical Condition Category; IQR, interquartile range; SD, standard deviation.

**Statistical Analysis**

We summarized patient and surgical characteristics for patients who underwent RP with descriptive statistics. Categorical variables were compared using Pearson’s  $\chi^2$  test and continuous variables using the Mann-Whitney *U* test. We performed difference-in-differences (DID) estimation, with bootstrapping to calculate the 95% confidence interval (CI), to assess the effect of hospital revenue on adoption trends. To compare postoperative outcomes,

we created unadjusted and adjusted regression models to evaluate the odds of postoperative complications, anastomotic strictures, incontinence, erectile dysfunction, and blood transfusion, as well as the incidence rate ratio for LOS. We accounted for clinically important confounders, including patient age, race, marital status, comorbidity (CMS-HCC), surgical approach (ORP vs MIRP), and baseline incontinence and erectile dysfunction. Additionally, we performed subgroup analysis on institutions where only MIRP was performed, examining differences in outcomes. Statistical analyses were performed using SAS version 9.3 (SAS Institute; Cary, North Carolina); all tests were 2-sided, and *P* < .05 was considered statistically significant.

**RESULTS**

In the study cohort, a total of 3366 men underwent radical prostatectomy in military hospitals compared with 1716 in civilian hospitals across the study period from 2005 to 2009. These surgeries occurred in 767 civilian and 36 military hospitals across the United States. Civilian hospitals were associated with an increased MIRP adoption by approximately 30% (DID estimation: 0.29; 95% CI, 0.19-0.39; *P* < .01) (Figure) over the course of the study. The disparity in MIRP utilization in favor of civilian hospitals was present during the entire study, but substantially increased beginning in 2008.

There were minimal differences between the 2 groups in terms of baseline characteristics (Table 1). Age and comorbidity status were similar between the 2 sectors, while there was a larger proportion of single men in civilian hospitals. There was a greater number of white, black, and Asian/Native American/other patients in the MHS (*P* < .0001), although the observed ethnic and racial differences may have been secondary to the larger number of unknown/missing data from civilian hospitals.

As for outcomes (Table 2), the median LOS between the patient cohorts was similar, although both the unadjusted and adjusted analyses demonstrated a reduced LOS for civilian hospitals (incidence risk ratio, 0.85; 95% CI, 0.83-0.87; *P* < .0001). Bivariate analyses showed that the shorter LOS for MIRP compared with ORP was more pronounced for civilian hospitals (MIRP: 1.74 days vs ORP: 2.52 days) than military hospitals (MIRP: 2.27 days vs ORP: 2.52 days). The proportion of patients receiving a blood transfusion within 30 days of the surgery was lower in the civilian hospitals (3.5% vs 8%; adjusted odds ratio, 0.44; 95% CI, 0.34-0.58; *P* < .0001). When we stratified this further by type of surgery performed, we found that the lower blood transfusion rate for MIRP was true for civilian hospitals (MIRP: 2.0% vs ORP: 8.9%) but not for military hospitals (MIRP: 4.4% vs ORP: 4.4%).

In contrast, the observed 30-day postoperative complication rates were highly comparable on both the unadjusted and adjusted analyses. Although the 30-day mortality rate was lower for civilian hospitals (0.03% vs 0.12%), this did not achieve statistical

**TABLE 2.** Unadjusted and Adjusted Postoperative Outcomes, Stratified by Healthcare System

Continuous Outcomes	Unadjusted Analysis			Adjusted Analysis	
	Military Institutions	Civilian Institutions	P	Incidence Risk Ratio (95% CI), Civilian vs Military <sup>a</sup>	P
Length of stay, median (IQR)	2 (1)	2 (2)	<.0001	0.85 (0.83-0.89)	<.0001
Categorical Outcomes				Odds Ratio (95% CI), Civilian vs Military <sup>b</sup>	P
30-day postoperative complications					
Any (Clavien grades 1-5)	33.6%	33.3%	.83	1.03 (0.91-1.18)	.61
Major (Clavien grades 3-5)	3.2%	3.1%	.80	0.93 (0.66-1.32)	.69
Mortality (Clavien grade 5)	0.12%	0.03%	.16	0.3 (0.025-3.59)	.34
30-day blood transfusion	8%	3.5%	<.0001	0.44 (0.34-0.58)	<.0001
Anastomotic stricture	9.1%	6.7%	.005	0.85 (0.67-1.07)	.16
Postoperative incontinence procedure	7.9%	7.3%	.51	0.94 (0.72-1.23)	.66
Postoperative ED procedure	5.1%	5.4%	.75	1.14 (0.83-1.57)	.40

CI indicates confidence interval; ED, erectile dysfunction; IQR, interquartile range.

<sup>a</sup>A multivariable zero-truncated negative binomial regression model was created using the characteristics listed in Table 1 as covariates.

<sup>b</sup>A multivariable logistic regression model was created using the characteristics listed in Table 1 as covariates.

significance. Similarly, we found that the development of an anastomotic stricture following surgery was lower among men in civilian hospitals (6.7% vs 9.1%), but our adjusted analysis failed to identify a statistically significant difference between men in the 2 cohorts. Assessment of long-term functional outcomes revealed that the utilization of surgery to address erectile dysfunction and incontinence was similar between men cared for in either healthcare environment. On subgroup analysis including only hospitals that performed MIRP, we also found no differences in terms of postoperative complications, incontinence, or erectile dysfunction (data not shown).

## DISCUSSION

In this study of TRICARE beneficiaries with prostate cancer, we found a substantially greater diffusion of MIRP among civilian institutions compared with MHS institutions between FY 2005 and FY 2010, and this difference was most pronounced after 2008, coinciding with the widespread adoption of robotic MIRP in the United States.<sup>13</sup> Despite the increasing disparity in MIRP diffusion, we observed similarity in surgical morbidity for these 2 healthcare environments based on postoperative complications and functional outcomes (ie, incontinence and erectile dysfunction). Our findings support the hypothesis that market forces may accelerate the adoption of clinical innovation, such as MIRP, among civilian hospitals, which rely heavily on generating revenue to deliver healthcare; however, the increased tendency to adopt MIRP was not associated with a meaningful improvement in surgical morbidity.

The strength of the current study is that we assessed men from a common insured population that were managed in 2 different

healthcare environments distinguished, in large part, by the role of hospital revenue source in healthcare delivery. Because the delivery of health services at civilian institutions is reliant on generating sufficient revenue, it is feasible that the motivation for technology adoption stems from an aim to maximize revenue by attracting new patients or avoiding a loss of patients.<sup>19,20</sup> In contrast to civilian hospitals, the MHS is supported by appropriations from the DoD. These budgetary decisions have an unusually broad scope of maintaining the health of all military personnel, their dependents, and retirees, as well as supporting military readiness, providing medical education, and improving public health. These competing priorities, coupled with the idiosyncrasies of federal appropriations laws and budgeting, may slow the adoption of technology within the MHS.

Prior population-based studies of nonfederal hospitals report that MIRP is associated with increased surgical volume. Chang et al demonstrated that surgeons, particularly high-volume surgeons, who adopted robotic MIRP experienced an increase in overall annual volume of RP.<sup>13</sup> Similarly, Makarov et al reported that hospitals that acquired the robotic platform were associated with a significant increase in annual RP volume, while hospitals without the robotic platform experienced a loss in volume.<sup>21</sup> Complementing the prior investigations, this study provides data that support the hypothesis that maximizing hospital revenue may have influenced the likelihood of adopting technology such as MIRP (Figure).

Despite the argument that hospital revenue drives technology dissemination, we also observed a substantial increase in the proportion of patients undergoing MIRP in the MHS during the final 2 years of the study. We speculated that this upward trend may be associated with a motivation to maintain parity with civilian

hospitals<sup>22</sup> and to keep TRICARE enrollees from seeking care at civilian hospitals to undergo MIRP. Surgeons at civilian hospitals may feel more of a need to learn new techniques to remain competitive for patient referrals in a “private” environment. In terms of reimbursement incentives at the physician level, a common misconception among nonurologists is that perhaps MIRP offers better reimbursement for the physician than ORP. However, this has not been found to be true; reimbursement to physicians for both ORP and MIRP has been found to be similar on a per-case basis.<sup>23</sup>

Regardless of the true motivation for this increased utilization by military hospitals of MIRP in the latter years of our study, we concluded that the adoption of technology is influenced by a multitude of factors, among which generating revenue is likely to represent one of the most important issues for civilian hospitals. Although both civilian and military hospitals were observed to have an increasing trend in utilization of MIRP, the proportion in military hospitals was lower (Figure) compared with civilian hospitals across all years. We hypothesized that this could be due to certain military facilities having an overall lower caseload of RP, which does not justify the establishment of an MIS program, and which has substantial upfront investment and ongoing maintenance costs. Although this may appear to be a lack of technological diffusion in the military system, it might actually point to prudent adoption of technology in select facilities that have the necessary surgical volume to allow for cost-conscious and safe dissemination.

Our study design permitted an evaluation of the possible impact of MIRP adoption on patient outcomes. We found that civilian hospital procedures were associated with a decrease in blood transfusions and a slightly shorter LOS, which are commonly noted among patients undergoing MIS procedures.<sup>9,24</sup> There was, however, no difference between procedures performed in civilian and military hospitals in the 30-day major complication rate (ie, Clavien grades 3-5) or in the long-term functional outcomes of postoperative incontinence and erectile function. The incidence of anastomotic strictures was also lower in civilian hospitals, but this did not achieve statistical significance in the adjusted analysis. Even with subgroup analysis focusing only on institutions offering MIRP, we did not detect any differences in outcomes between civilian and military hospitals, suggesting that our findings are not influenced by unmeasured factors associated with the availability of MIRP (eg, the availability of the robotic platform).

Our finding of relative equivalence in morbidity between healthcare systems, despite differences in the adoption of MIRP, is consistent with contemporary population-based studies that report mixed results regarding the perioperative outcomes of ORP and MIRP.<sup>8,9,11,25</sup> There are, however, unmeasured factors, such as differences in the time for convalescence, total pain medication use, and patient satisfaction, which may preferentially favor MIRP given the decrease in surgical trauma associated with MIS.<sup>26</sup> In

our adjusted model, LOS and blood transfusion were slightly reduced for civilian hospitals even after adjusting for surgical approach (Table 2), possibly reflecting advantages at the civilian hospitals that are not quantified by the Clavien classification system for surgical complications or captured by assessment of functional outcomes.

Given the absence of a morbidity improvement for MIRP, we concluded that its rapid adoption among civilian hospitals was not based on data in the medical literature. In fact, well-executed studies regarding MIRP are only recently available.<sup>8,9,11,25</sup> There are challenging obstacles for critical evaluation through a randomized controlled trial, most notably: 1) the difficulty in accruing patients willing to defer their choice for management to randomization, 2) the impracticality in blinding patients and surgeons, and 3) the challenges in controlling for surgeon learning curve and variations in technique.<sup>27</sup> We surmised that the promise of new surgical innovation to improve outcomes is intensely attractive, particularly for a procedure like RP, which is associated with detrimental functional issues, such as urinary incontinence and erectile dysfunction, thereby creating pressure for surgeons and hospitals to explore new technologies. Consequently, despite the absence of Level I evidence demonstrating superiority or equivalence of MIRP over ORP, a large percentage of surgeons in the United States has now adopted robotic MIRP,<sup>13</sup> and the majority of RP surgeries are now performed with the robotic platform.<sup>8-10</sup>

### Limitations

Our findings must be interpreted within the context of several important limitations to our study design. First, we used administrative data from TRICARE (claims for reimbursement for civilian hospitals and utilization records for military hospitals), which is not designed for documenting a patient’s clinical course and outcome. It is possible that more granular clinical information might have altered the associations we report or revealed new relationships not identified in the current study. However, the TRICARE claims data share many similarities with Medicare claims data, which have been used extensively to evaluate surgical outcomes.<sup>28</sup>

Second, we could not adjust for tumor stage and grade because these characteristics are not reliably captured with claims data; however, in men with prostate cancer, tumor characteristics are unlikely to influence the postoperative complications, LOS, and long-term functional outcomes. Third, to assess for postoperative urinary incontinence and erectile dysfunction, we considered surgical intervention as a proxy for functional status. Admittedly, we cannot exclude the possibility that there may be a disparity in the threshold to undergo those surgical interventions between civilian and military institutions.

Fourth, although we had hospital volume data for military hospitals, we did not have that same reliable data for civilian hospitals, precluding us from adjusting for surgical volume as a possible

confounder, especially when this has been previously shown to affect postoperative outcomes.<sup>29,30</sup> Lastly, we did not have reliable estimates for costs and revenues to comprehensively assess the differential amount of revenue generated by adoption of MIRP over ORP; this may have garnered additional insights regarding the potential financial incentives of adopting MIRP.

## CONCLUSIONS

To our knowledge, this is the first study assessing the potential impact of the type of healthcare delivery system on the adoption of MIRP in the United States. Based on TRICARE enrollee data, we observed that adoption was more rapid among civilian hospitals, which are comprised of institutions heavily reliant on generating hospital revenue to deliver health services. Further analysis, however, showed that the increased use of MIRP did not translate into a marked improvement in outcomes, thus highlighting the potential dangers of embracing new clinical innovations prior to the availability of evidence showing benefit. Our findings are particularly relevant as the delivery of healthcare in the United States is undergoing dramatic change. Future work should focus on determining if the goals of cost containment and of revenue based on quality, the principles underlying accountable care organizations, promote or repress clinical innovation in the United States. ■

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