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# Risk of Incisional Hernia after Minimally Invasive and Open Radical Prostatectomy

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# Abstract

**Purpose**—The number of radical prostatectomies has increased. Many urologists have shifted from the open surgical approach to minimally invasive techniques. It is not clear whether the risk of post-prostatectomy incisional hernia varies by surgical approach.

**Materials and Methods**—In the linked Surveillance, Epidemiology, and End Results (SEER)-Medicare dataset we identified men age 66 and older who had minimally invasive (MIRP) or open radical prostatectomy (ORP) for prostate cancer diagnosed 2003–2007. The main outcome was incisional hernia repair identified in Medicare claims following prostatectomy. We also examined the frequency of umbilical, inguinal and other hernia repairs.

**Results**—We identified 3,199 patients who had MIRP and 6,795 who had open radical prostatectomy ORP. The frequency of incisional hernia repair was 5.3% (median follow-up 3.1 years) in the MIRP group and 1.9% (median follow-up 4.4 years) in the ORP group, corresponding to incidence rates of 16.1 and 4.5 per 1000 person-years for MIRP and ORP, respectively. Compared with ORP, MIRP was associated with a more than 3-fold increased risk of incisional hernia repair, controlling for patient and disease characteristics (adjusted hazard ratio 3.39, 95% CI, 2.63–4.38, p <0.0001). MIRP was associated with an attenuated but increased risk of any hernia repair compared with ORP (adjusted hazard ratio 1.48, 95% CI 1.29–1.70, p <0.0001).

**Conclusions**—MIRP was associated with a significantly increased risk of incisional hernia compared with ORP. This is a potentially remediable complication of prostate cancer surgery that warrants increased vigilance with respect to surgical technique.

## Keywords

analysis.

prostatic neoplasms; prostatectomy; inguinal hernia; incisional hernia; umbilical hernia

#### CONFLICT OF INTEREST

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None of the authors has any conflict of interest to declare.

# INTRODUCTION

Since the introduction of the prostate specific antigen (PSA) test, one in six men is estimated to be diagnosed with prostate cancer in his lifetime<sup>1</sup> Subsequently, the number of radical prostatectomies (RPs) has increased dramatically.<sup>2</sup> RP can be performed by open (retropubic or perineal) or minimally-invasive (laparoscopic or robot-assisted laparoscopic) approaches.<sup>3</sup> Management practices have evolved, and most urologists have shifted away from the open approach and adopted minimally invasive techniques. While there are well-known surgical side-effects,<sup>4</sup> there are other, less described, but not infrequent and potentially serious, complications; one being the development of an incisional hernia.<sup>5–6</sup> Such hernias require surgical repair, resulting in short-term patient disability and increased health care costs.

Inguinal hernia after open radical prostatectomy (ORP) using the retropubic approach is well-described.<sup>7</sup> Recent reports suggest that the frequency of inguinal hernia within 4 years after surgery is 12%–21% after ORP<sup>8–9</sup> and 6% after minimally-invasive radical prostatectomy (MIRP).<sup>10</sup>

While incisional hernia is rare after ORP, less than 1%, reports from single-surgeon or single-institution series suggest an incidence of port-site (umbilical/incisional) hernias of up to 5% after MIRP.<sup>5,6,11,12</sup> Because an incisional hernia is typically related to surgical technique in closing the fascia, it is important to understand the true incidence of this complication in order to focus attention on strategies to improve outcomes. Importantly, incisional hernias can be associated with significant morbidity in the presence of small-bowel obstruction that, in addition to repair of the hernia, requires bowel resection.<sup>13</sup> Our objectives were to describe the frequency of hernia repairs after RP and estimate the impact of surgical approach on the likelihood of incisional hernia. We hypothesized that there would be a higher risk of incisional hernia repairs associated with MIRP compared to ORP.

## **METHODS**

#### **Data Source**

The primary data source was the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results (SEER)-Medicare database, which links information from the SEER cancer registry program with Medicare claims and enrollment records. SEER is a consortium of population-based cancer registries in selected states and geographic areas covering approximately 26% of the US population.<sup>14</sup> SEER registries collect data on disease site and extent, first course of cancer-directed therapy and sociodemographic characteristics, with active follow-up for date and cause of death. Medicare is the primary health insurer for 97% of Americans aged 65 years and older, and cover inpatient hospital care (Part A) and outpatient care and physician services (Part B).<sup>15</sup> Compared with the population of all US adults aged 65 and older, the SEER-Medicare population has a similar age and sex distribution but has more residents of urban and affluent areas and a smaller proportion of nonwhite individuals.<sup>14</sup>

The SEER-Medicare files were used in accordance with a data use agreement from NCI, and the study was reviewed by the institutional review board at Memorial Sloan-Kettering Cancer Center and deemed exempt from informed consent requirements.

#### Cohort

We identified men age 66 years or older diagnosed with prostate cancer between 2003 and 2007 who were treated with MIRP or ORP. Men who were diagnosed only at the time of death, who were enrolled in a managed care plan in the year prior to or at any time after

diagnosis, or who lacked complete Medicare coverage (parts A and B) were excluded. We also excluded men who received radiation therapy after RP.

#### **Outcomes and Predictors**

The primary outcome was receipt of an incisional hernia repair procedure, identified in Medicare claims at any time after the date of RP. We repeated this analysis restricting the primary outcome to incisional hernia repairs within 36 months of RP. We also examined the frequency of any type of hernia repair, including umbilical, inguinal and other hernia (see procedure codes in Appendix Table 1). When multiple claims or multiple procedure codes within a single claim indicated that an incisional hernia and any other type of hernia were repaired on the same day, we classified the repair as incisional. If repair of an inguinal (umbilical) hernia occurred on the same day as another type of non-incisional hernia repair the procedure was classified as inguinal (umbilical). If there were claims for inguinal and umbilical hernia repair on the same day, the procedure was classified other hernia repair

The predictor of interest was surgical approach, classified as open or minimally invasive. Surgical procedures were identified by Healthcare Common Procedural Coding System (HCPCS) codes (55866 for MIRP and 55840, 55842, and 55845 for ORP) in physician claims. Demographic covariates included patient age at diagnosis, race, geographic location, and marital status. Median income in the census tract of residence served as a marker of socioeconomic status. Clinical covariates included clinical tumor stage, Gleason score, lymph node involvement, and year of surgery. Comorbidity was estimated using a modification of the Charlson comorbidity score based on inpatient, outpatient, and physician claims in the year before prostate cancer diagnosis.<sup>16</sup> We assessed the use of medical and surgical androgen deprivation therapy (ADT) by identifying claims for GnRH agonists and bilateral orchiectomy at any time after diagnosis. We also identified from patients who had a hernia repair in the year prior to prostatectomy, including those repaired on the day of radical prostatectomy.

For each patient treated before May 2007, we estimated procedure-specific annual surgeon volume as the number of procedures of the same type (ORP or MIRP) performed by the surgeon in the previous 365 days, including that patient's procedure, based on provider claims among all prostate cancer patients in the SEER-Medicare database. For patients treated in 2003, annual surgeon volume was based on procedures during the calendar year. In May 2007 the National Provider Identifier (NPI) replaced the Unique Physician Identifier Number (UPIN) as the required identifier for Medicare services.

#### **Statistical Analysis**

Unadjusted associations between surgical approach and patient demographic and disease characteristics were assessed using chi-square statistics. The impact of surgical approach on the risk of hernia repair was evaluated in a time-to-event framework, where the time origin was date of RP, and patients who did not have an event were censored at the time of death or end of follow-up. Multivariable proportional hazards regression was used to estimate the impact of surgical approach on incisional hernia repair, controlling for demographic, disease, and health characteristics. Receipt of ADT was analyzed as a time-dependent covariate, with exposure identified at the time of first Medicare claim for ADT after RP, or at RP if it was identified between the month of prostate cancer diagnosis and the date of RP. Hazard ratios, 95% confidence intervals, and 2-sided p-values were estimated for each covariate. In a separate analysis of men who had RP before May 2007, we included annual surgeon volume as a predictor of incisional hernia repair. All analyses were performed in SAS, version 9.2 (SAS Institute Inc., Cary, NC).

# RESULTS

We identified 9,994 men who had surgery for prostate cancer, including 3,199 (32%) patients who had MIRP and 6,795 (68%) who had ORP. Distributions of age and race were similar in the two groups. Compared with ORP, men who had MIRP were more likely to reside in urban areas and census tracts with higher median income. They also generally had a higher Gleason score, but a lower comorbidity score. Six percent of men in both groups had a hernia repair procedure in the year prior to or on the day of prostate cancer surgery. Minimally invasive prostatectomies, as a proportion of all RP's, increased over time. (Appendix Table 2)

The frequency of post-RP incisional hernia repair was 5.3% in those treated with MIRP (median follow-up 3.1 years) and 1.9% in those treated with ORP (median follow-up 4.4 years) (Table 1). These estimates correspond with incidence rates of 16.1 and 4.5 per 1000 person-years, respectively. Most of the incisional hernia repairs were performed within 36 months of RP, with only 10 of 168 (MIRP) and 31 of 131 (ORP) procedures performed after this time period. When we examined the risk of any hernia repair after prostate cancer surgery, inguinal hernia repairs were the most common first procedure in both the MIRP (6.4%) and ORP (7.7%) groups, followed by incisional hernia repair. Umbilical and other types of hernia repair were observed in about 1.2% of men who had MIRP and <1% of men who had ORP. MIRP was associated with a more than three-fold increased risk of incisional hernia repair compared with ORP (adjusted hazard ratio 3.39, 95% CI, 2.63–4.38, p <0.0001), controlling for patient and disease characteristics (Appendix Table 3). Men age 70–74 had an increased risk of incisional hernia repair, as did those with Charlson comorbidity score of 2 or greater and those with a hernia repair in the year prior to RP. Results were similar when the analysis was restricted to incisional hernia repair occurring within 36 months of RP. When the outcome was we examined any type of hernia repair, MIRP was associated with an attenuated but still statistically significant increased risk compared with ORP (adjusted hazard ratio 1.48, 95% CI 1.29–1.70, p <0.0001). In a separate model including surgeon volume for patients who had RP prior to May 2007, higher surgeon volume, modeled as a continuous covariate, was associated with an increased risk of incisional hernia repair (adjusted hazard ratio 1.01, 95% CI 1.00-1.02, p=0.0108) Controlling for surgeon volume, the risk of incisional hernia repair associated with MIRP was still more than double the risk for men who had ORP (adjusted hazard ratio 2.67, 95% CI 1.97–3.61, p<0.0001).

#### DISCUSSION

In this population-based study of older men, MIRP was associated with a more than 3-fold increased risk of incisional hernia repair compared with ORP, controlling for patient and disease characteristics. This information is important for patients weighing the risks and benefits of local treatment options for prostate cancer. Recognizing that surgical approach increases the likelihood of subsequent incisional hernia repair should prompt surgeons to consider alterations in technique to reduce this risk.

Incisional hernia represents a potentially serious complication to minimally invasive surgery, since most require further surgical intervention.<sup>17</sup> In general, incisional hernias represent a technical issue. For minimally-invasive surgery, incisional hernias have been reported to occur more commonly with increasing port size and in cases that use the port site for tissue extraction as occurs in RP.<sup>5</sup> Some recommend closing the supraumbilical incision with an interrupted suturing technique,<sup>12</sup> although others favor the continuous approach.<sup>18</sup>

We can speculate in reasons to why MIRP was associated with a higher incisional hernia occurrence than ORP. Perhaps, the supra-umbilical location of the optical port and excision site in MIRP compared to the infra-umbilical incision for ORP, is a source of abdominal wall muscle weakness and increased risk of hernia formation. Strategies to optimize surgical technique are constantly evolving and moving the extraction site to below the umbilicus may mitigate the risk of hernia development in MIRP. However, most surgeons performing robot-assisted RP suggest placing the optical trocar at the level of or just above the umbilicus.<sup>19</sup>

In one single-surgeon MIRP series, incisional hernias occurred more often after a vertical than after a transverse incision,<sup>6</sup> corroborating a Cochrane review of 7 trials of abdominal surgery in which a significant difference was seen in favor of the transverse incision over the midline.<sup>20</sup> In gynecologic surgery, the transverse lower abdominal incision is the the standard incision because it is believed to help prevent incisional hernia formation. In a prospective randomized trial of patients undergoing ORP, no incisional hernias occurred at the 6-month follow-up regardless of the type of laparotomy (standard vertical vs. Pfannenstiel transverse).<sup>21</sup> Despite the small sample size, the study may support the idea that mechanical factors are important in incisional hernia formation and may further explain the lower incisional hernia rate in infra-umbilical incisions more common in ORP.

Inguinal hernia is a well-known complication after ORP, with an incidence between 12% and 21% within 4 years following surgery.<sup>8</sup> Compared to historic studies<sup>10</sup>, we identified a lower incidence of inguinal hernia repair after ORP (7.7%). We can speculate in reasons for this. A shorter lower midline abdominal incision is becoming routine. The incidence of post-RP inguinal hernia is higher after ORPs performed through a conventional lower midline incision (pubis to umbilicus; approximately 15 cm) whereas ORPs performed through a so called minilaparotomy<sup>22</sup> (5–8 cm incision) have reported rates in the range of 1.5%–3%.<sup>8</sup> Further, recognition of an increased risk of inguinal hernia after ORP has prompted some surgeons to recommend placing a prophylactic suture lateral to the inguinal ring.<sup>23, 24</sup>

Risk factors for hernias include mechanical/technical factors (e.g., surgeon experience, incision length, method of fascial closure, and trocar type for port placement), and patient factors such as obesity and diabetes.<sup>5, 11</sup> We identified surgical approach as a risk factor for incisional hernia repair. MIRP has many risk factors for incisional hernia inherent to the procedure including expansion of the umbilical trocar-site for specimen extraction and variability in guidelines recommending closure of instrument incisions. Furthermore, the location of the optical port or extraction site in relation to the umbilicus may impact the risk of hernia development.

The relationship between surgical volume and outcomes is well established.<sup>25</sup> In our study, procedure-specific surgeon volume in the year prior to index RP was statistically associated with developing an abdominal hernia after RP (AHR 1.01, 95% CI 1.00–1.02), albeit with a somewhat attenuated risk. This suggests that the technical aspects of closing the abdominal incision do not improve with greater experience, or possibly that less experienced surgical assistants are assigned the task of closing the incisions of more experienced surgeons. Because incisional hernia is generally a preventable complication, more attention to this part of the procedure is warranted.

Several limitations of our analysis should be noted. We identified surgical repairs for hernia, rather than the incidence of hernia diagnosis. However, surgically repaired hernias likely represent the most severe cases, and therefore serve as a clinically relevant endpoint and one that may be more reliably identified in health insurance claims. While we were able to control for numerous potential confounders, we could not control for smoking history or

body mass index, two risk factors associated for hernia. We also had no information regarding patient preferences, physician recommendations for treatment, or other factors that may be associated with surgical approach, the likelihood of a hernia repair procedure or both. Additionally, while we identified hernias repairs prior to prostate cancer surgery as a risk factor for a new incisional hernia following RP, we were not able to examine claims more than a year prior to RP for all patients. Regarding inguinal hernia repair, we identified our outcome as cases of hernia repair using procedure codes in claims data, which represents a clinically relevant finding compared to diagnosis of a hernia using these data. This likely resulted in an underestimate of the risk of hernia incidence after RP. Furthermore, our study is population-based and represents a contemporary cohort of patients compared with may explain, in part, the discrepancy in hernia incidence with previous studies. Finally, our results may not be generalizable to prostate cancer patients younger than 66 years.

#### CONCLUSION

Our results suggest that hernia may be more common after RP than previously reported, and the risk of incisional hernia repairs is more likely after MIRP than ORP. This represents an issue related to surgical technique in closing the fascia and is thus a potentially preventable complication that warrants attention in order to reduce patient morbidity.

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#### Key of definitions of abbreviations

SEER	Surveillance, Epidemiology, and End Results
RP	Radical Prostatectomy
MIRP	Minimally-Invasive Radical Prostatectomy
ORP	Open Radical Prostatectomy
NCI	National Cancer Institute
HCPCS	Healthcare Common Procedural Coding System
ADT	Androgen Deprivation Therapy
AHR	Adjusted Hazard Ratio

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#### Table 1

#### Frequency of hernia repair following prostatectomy

	MIRP (N = 3,199)		ORP (N = 6,795)	
	No. Pts	% of Pts	No. Pts	% of Pts
Incisional hernia repair	168	5.3%	131	1.9%
Incisional hernia repair within 36 months of prostatectomy	158	4.9%	100	1.5%
Any hernia repair	397	12.4%	686	10.1%
First procedure:				
Inguinal hernia repair	204	6.4%	521	7.7%
Incisional hernia repair	154	4.8%	112	1.7%
Umbilical hernia repair	17	0.5%	31	0.5%
Other hernia repair	22	0.7%	22	0.3%

MIRP: Minimally invasive radical prostatectomy

ORP: Open radical prostatectomy

#### Appendix Table 1

#### ICD-9 Procedure and CPT/HCPCS Codes

Procedure	ICD-9 Procedure	CPT/HCPCS
MIRP		55866
ORP		55840, 55842, 55845
Radiotherapy/ Brachytherapy	92.21 – 92.27	77400 – 77420, 77425, 77427, 77430, 77431, 77432, 77470, 77520, 77522, 77523, 77525, 77789, 55859, 77750, 77761, 77762, 77763, 77776, 77777, 77778, 77781, 77782, 77783, 77784, C2632, Q3001
Incisional Hernia Repair		48955, 49560, 49561, 49565, 49566, 49568
Inguinal Hernia Repair	53.00 - 53.05	49505, 49507, 49525, 49650
Umbilical Hernia Repair	53.40 - 53.49	49585, 49587, 49652, 49653
Other Hernia Repair	53.50 - 53.69	

#### Appendix Table 2

Characteristics of the cohort by surgical approach

	MIRP		ORP		
	No.	%	No.	%	p-value
Total N	3,199	32%	6,795	68%	:
Age at diagnosis					< 0.0001
66–69	1,797	56%	3,689	54%	
70–74	1,129	35%	2,351	35%	
75–59	249	8%	598	9%	
80+	24	1%	157	2%	
Race					< 0.0001
White	2,767	86%	5,913	87%	
Black	165	5%	455	7%	
Other	267	8%	427	6%	
Census tract median income					< 0.0001
1st quartile	611	19%	1,844	27%	
2nd quartile	682	21%	1,775	26%	
3rd quartile	839	26%	1,617	24%	
4th quartile	1,028	32%	1,430	21%	
Unknown	39	1%	129	2%	
Urban-rural residence					< 0.0001
Metropolitan	2,884	90%	5,673	83%	
Non-metropolitan	315	10%	1,122	17%	
Region					< 0.0001
Northeast	517	16%	828	12%	
South	582	18%	1,041	15%	
Midwest	366	11%	821	12%	
West	1,834	57%	4,105	60%	
Marital status					< 0.0001
Married	2,564	80%	5,465	80%	
Not married	430	13%	1,029	15%	
Unknown	205	6%	301	4%	
Clinical T-stage					< 0.0001
T1	1,857	58%	3,042	45%	
T2	1,264	40%	3,313	49%	
T3/T4	54	2%	155	2%	
Unknown	24	1%	285	4%	
Gleason score					< 0.0001
2–6	1,160	36%	3,012	44%	
7+	2,024	63%	3,733	55%	
Unknown	15	0%	50	1%	

	MIRP		ORP		
	No.	%	No.	%	p-value
Lymph node involvement					< 0.0001
Negative	3,092	97%	6,524	96%	
Positive	30	1%	189	3%	
Unknown	77	2%	82	1%	
Androgen deprivation therapy					< 0.0001
Yes	393	12%	1,044	15%	
No	2,806	88%	5,751	85%	
Charlson comorbidity score					0.0002
0	2,575	80%	5,219	77%	
1	466	15%	1,169	17%	
2+	158	5%	407	6%	
Previous hernia					0.7101
Yes	191	6%	393	6%	
No	3,008	94%	6,402	94%	
Surgery year					< 0.0001
2003	112	4%	1,320	19%	
2004	333	10%	1,563	23%	
2005	517	16%	1,332	20%	
2006	791	25%	1,206	18%	
2007	1,176	37%	1,189	17%	
2008	270	8%	185	3%	

MIRP: Minimally invasive radical prostatectomy

ORP: Open radical prostatectomy

#### Appendix Table 3

Impact of surgical approach and patient characteristics on risk of incisional hernia repair after prostatectomy

Characteristic	Adjusted Hazard Ratio (95% CI)	P-value
Surgical approach		
ORP	Reference	< 0.0001
MIRP	3.39 (2.63 – 4.38)	
Age at diagnosis		
66–69	Reference	0.0005
70–74	1.67 (1.31 – 2.13)	
75–59	1.45 (0.96 – 2.21)	
80+	1.00 (0.36 - 2.79)	
Race		
White	Reference	0.0024
Black	0.69 (0.38 - 1.24)	
Other	0.31 (0.15 - 0.62)	
Census tract median income	e	
1st quartile	Reference	0.9952
2nd quartile	1.03 (0.72 - 1.47)	
3rd quartile	0.97 (0.68 - 1.40)	
4th quartile	0.96 (0.67 – 1.39)	
Unknown	0.97 (0.39 – 2.44)	
Urban-rural residence		
Metropolitan	Reference	0.0393
Non-metropolitan	0.63 (0.41 - 0.98)	
Region		
Northeast	Reference	0.6944
South	1.09 (0.68 - 1.75)	
Midwest	1.22 (0.76 – 1.96)	
West	1.22 (0.85 – 1.76)	
Marital status		
Not married/unknown	Reference	0.656
Married	0.94 (0.70 - 1.25)	
Clinical T-stage		
T1	Reference	0.0002
T2	1.07 (0.84 – 1.36)	
T3/T4	1.25 (0.51 – 3.07)	
Unknown	3.33 (1.95 - 5.68)	
Gleason score		
2–7	Reference	0.0845
8+	0.81 (0.64 - 1.03)	
Lymph node involvement		
Negative	Reference	0.4606

Characteristic	Adjusted Hazard Ratio (95% CI)	P-value
Positive	0.43 (0.11 – 1.76)	
Unknown	0.84 (0.37 – 1.90)	
Androgen deprivation the	rapy *	
No	Reference	0.524
Yes	0.81 (0.43 – 1.54)	
Charlson comorbidity sco	re	
0	Reference	0.0369
1	0.92 (0.66 – 1.28)	
2+	1.70 (1.11 – 2.61)	
Previous hernia		
No	Reference	< 0.0001
Yes	2.95 (2.15 - 4.05)	
Surgery year	0.99 (0.91 – 1.09)	0.8657

MIRP: Minimally invasive radical prostatectomy

ORP: Open radical prostatectomy

\* Androgen deprivation therapy modeled as a time-dependent covariate

Analysis excludes n=65 patients [0 events] with unknown Gleason score