

## Special Article

## VARIATIONS IN MORBIDITY AFTER RADICAL PROSTATECTOMY

COLIN B. BEGG, PH.D., ELYN R. RIEDEL, M.A., PETER B. BACH, M.D., M.A.P.P., MICHAEL W. KATTAN, PH.D.,  
DEBORAH SCHRAG, M.D., M.P.H., JOAN L. WARREN, PH.D., AND PETER T. SCARDINO, M.D.**ABSTRACT**

**Background** Recent studies of surgery for cancer have demonstrated variations in outcomes among hospitals and among surgeons. We sought to examine variations in morbidity after radical prostatectomy for prostate cancer.

**Methods** We used the Surveillance, Epidemiology, and End Results–Medicare linked data base to evaluate health-related outcomes after radical prostatectomy. The rates of postoperative complications, late urinary complications (strictures or fistulas 31 to 365 days after the procedure), and long-term incontinence (more than 1 year after the procedure) were inferred from the Medicare claims records of 11,522 patients who underwent prostatectomy between 1992 and 1996. These rates were analyzed in relation to hospital volume and surgeon volume (the number of procedures performed at individual hospitals and by individual surgeons, respectively).

**Results** Neither hospital volume nor surgeon volume was significantly associated with surgery-related death. Significant trends in the relation between volume and outcome were observed with respect to postoperative complications and late urinary complications. Postoperative morbidity was lower in very-high-volume hospitals than in low-volume hospitals (27 percent vs. 32 percent,  $P=0.03$ ) and was also lower when the prostatectomy was performed by very-high-volume surgeons than when it was performed by low-volume surgeons (26 percent vs. 32 percent,  $P<0.001$ ). The rates of late urinary complications followed a similar pattern. Results for long-term preservation of continence were less clear-cut. In a detailed analysis of the 159 surgeons who had a high or very high volume of procedures, wide surgeon-to-surgeon variations in these clinical outcomes were observed, and they were much greater than would be predicted on the basis of chance or observed variations in the case mix.

**Conclusions** In men undergoing prostatectomy, the rates of postoperative and late urinary complications are significantly reduced if the procedure is performed in a high-volume hospital and by a surgeon who performs a high number of such procedures. (N Engl J Med 2002;346:1138-44.)

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**S**TUDIES of the outcomes of surgery for cancer have typically focused on the number of procedures performed at a hospital (hospital volume) as a proxy for the experience of the surgeons who operate at the hospital. The observation that there are consistent relations between increased numbers of operations and better outcomes among patients has led to in-depth investigations to determine the differences in the processes of care that explain the variations. If the trends are especially strong, an argument can be made for regionalizing care on the basis of hospital volume alone — that is, referring patients to high-volume hospitals.<sup>1</sup> Procedures for which strong and consistent trends have been observed are pancreatotomy<sup>2-6</sup> and esophagectomy.<sup>5,7</sup> More common procedures, including primary surgery for colon cancer,<sup>8-10</sup> breast cancer,<sup>11,12</sup> and lung cancer,<sup>13</sup> have also been studied. The latter studies have revealed smaller trends than those observed in the studies of pancreatotomy and esophagectomy, but their importance to public health may be greater.<sup>14</sup>

Radical prostatectomy is widely used as primary treatment in patients with early-stage prostate cancer. Although decreases in postoperative mortality have been associated with increases in hospital volume, prostatectomy is associated with a very low overall operative mortality — approximately 0.5 percent.<sup>15,16</sup> However, the potential for postoperative and long-term complications after this procedure has been well documented.<sup>17-25</sup> Thus, it is plausible that variations in surgical technique and follow-up care have a substantial effect on postoperative morbidity. We used the Surveillance, Epidemiology, and End Results (SEER)–Medicare data base, a population-based resource of newly diagnosed cases of cancer and linked Medicare claims, to study hospital volume and the number of procedures performed by individual surgeons (surgeon volume) in relation to outcomes after radical prostatectomy.

From the Health Outcomes Research Group, Department of Epidemiology and Biostatistics (C.B.B., E.R.R., P.B.B., M.W.K., D.S.), and the Department of Urology (M.W.K., P.T.S.), Memorial Sloan-Kettering Cancer Center, New York; and the Applied Research Branch, National Cancer Institute, Bethesda, Md. (J.L.W.). Address reprint requests to Dr. Begg at the Department of Epidemiology and Biostatistics, Memorial Sloan-Kettering Cancer Center, 1275 York Ave., Box 44, New York, NY 10021, or at [beggc@msskcc.org](mailto:beggc@msskcc.org).

## METHODS

### Sources of Data

The SEER–Medicare data base has been described in detail elsewhere.<sup>26</sup> The SEER Cancer Registries include data from six metropolitan areas and five states and encompass approximately 14 percent of the population of the United States.<sup>27</sup> The Medicare program provides benefits to the majority of people 65 years old or older. All claims are reported individually to the Centers for Medicare and Medicaid Services, except those for patients enrolled in health maintenance organizations. The latter patients were excluded from our analyses.

### Study Cohort

First, we selected all patients 65 years old or older who were listed in the SEER data base as having received a diagnosis of prostate cancer between 1992 and 1996 (the index period) (77,796 patients). We limited the cohort by excluding patients who were not treated in a SEER state, were not enrolled in both Part A and Part B of Medicare, or were not listed in Medicare records as having undergone prostatectomy within six months after the diagnosis. After these exclusions, 11,522 patients remained in the analysis. For studies of variations according to surgeon, the cohort was further reduced to the 10,737 patients whose surgeons could be identified in Medicare records. For the 198 patients with more than one surgeon, we selected the surgeon who had the larger volume of patients for analysis.

### Outcomes

We examined four general classes of outcome: postoperative death, postoperative complications, late urinary complications, and long-term incontinence. Postoperative death was defined as death within 30 days or, alternatively, death within 60 days after prostatectomy, with time measured from the date of hospitalization as a proxy for the date of surgery. Postoperative complications were defined as potentially life-threatening events during the 30 days after surgery in the following categories: cardiac, respiratory, or vascular events; the need for reoperation; bleeding; and other events, such as renal failure and shock. Late urinary complications were defined as bladder-neck obstruction, urethral or ureteral strictures, intestinal or vesical fistulas, pelvic abscess, or any complication that resulted in early, definitive treatment of incontinence. These were classified either as complications identified by symptoms or procedures during the period from 31 to 365 days after surgery. Events deemed “major” were characterized by diagnoses of illnesses or invasive procedures associated with unanticipated risks or adverse effects on health or organ function. Ninety-four percent of the patients who had late urinary events had either bladder-neck obstruction or urethral strictures. Likewise, long-term incontinence was defined on the basis of symptoms leading to a diagnosis of incontinence or the use of corrective procedures or specific diagnostic tests (such as urodynamic tests) more than one year after surgery. Major incontinence-related events included the use of a subgroup of specific corrective procedures (such as periurethral injections of collagen or placement of an artificial urinary sphincter) or invasive diagnostic procedures.

To maximize the ascertainment of events, all the symptom and procedure codes used to identify these outcomes were derived from both outpatient and inpatient claims.<sup>28</sup> Details are provided in Supplementary Appendix 1 (available with the full text of this article at <http://www.nejm.org>). Follow-up data were available through 1998.

### Predictors of Outcome

We determined hospital volume and surgeon volume according to the numbers of procedures performed in members of the cohort during the period from 1992 through 1996. Hospitals and surgeons

were classified into four volume categories on the basis of quartiles of the patient cohort. In subsequent analyses, we examined treatment by individual high-volume surgeons as a potential predictor of patients' outcome. The latter analyses were restricted to surgeons who performed a minimum of 20 procedures during the five-year study and hence were in the two highest quartiles of volume (high and very high); the analysis of surgeons with smaller volumes would be less reliable. The following patient-related covariates were used for risk adjustment: age, race, stage of disease at diagnosis, and the extent of coexisting illnesses according to the Romano modification<sup>29</sup> of the Charlson index.<sup>30</sup> The Romano–Charlson index is a weighted count of designated coexisting illness, excluding cancer, and was evaluated for the 12-month period before surgery.

### Validation of Measures of Volume

The classifications of hospital volume and surgeon volume may have been skewed by the considerable number of procedures performed in men less than 65 years of age, who were not included in our cohort. We therefore used two additional sources of data for validation. First, we identified all men who underwent a prostatectomy in New York State between 1994 and 1996 from the state discharge registry and calculated hospital volume in two ways: with all the patients and with only those 65 years of age or older. The Spearman rank-correlation coefficient for the association between these two calculations was 0.96. We evaluated surgeon volume in the same manner; the correlation coefficient was 0.91. We further evaluated our classifications of hospital volume by analyzing the 72 hospitals represented in both our cohort and the Nationwide Inpatient Sample<sup>31</sup> for the year 1997. Although the accrual periods do not overlap, the Spearman rank-correlation coefficient for the association between the two calculations of volume was 0.75.

### Validation of Outcomes

In the ideal validation of outcomes, complications reported on claims would be compared with clinical complications observed directly. For late urinary complications, we compared Medicare claims records with follow-up data obtained by questionnaire in the Prostate Cancer Outcomes Study (PCOS).<sup>22</sup> In this comparison, participants 65 years of age or older who had undergone radical prostatectomy were asked specifically about the treatment of urinary strictures.<sup>32</sup> Urinary strictures constituted 70 percent of the late urinary complications in our cohort. Of 337 respondents one year after surgery, 52 (15 percent) indicated that they had been treated for a stricture during the first year; 56 such patients (17 percent) were identified on Medicare claims. Using the PCOS questionnaire as the standard, we found that review of Medicare claims had a sensitivity of 83 percent and a specificity of 95 percent for identifying the occurrence of this complication.

We used a similar strategy to evaluate incontinence 24 months after prostatectomy. We defined severe incontinence as leakage or absence of urinary control occurring more than twice a day, combined with a response on the PCOS questionnaire that this represented a “big” or “moderate” problem. Of the 287 respondents at 24 months, 33 (11 percent) met the criterion for severe incontinence; 31 such patients (11 percent) were identified on the basis of Medicare claims. However, only 12 of the 287 men (4 percent) were classified as severely incontinent by both approaches (sensitivity of Medicare-claims review, 39 percent; specificity, 92 percent). Thus, although Medicare claims can be used to evaluate the occurrence of late urinary complications (such as strictures), the relatively low sensitivity of this approach for detecting incontinence may limit the power to detect an effect of hospital or surgeon volume on this outcome.

We did not have data that could be used to validate postoperative complications directly. However, another study found that Medicare claims have a high degree of validity for detecting complications of surgery, in that 89 percent of cases identified through review of

Medicare claims as involving complications of surgery were corroborated on review of the medical record.<sup>33</sup>

**Statistical Analysis**

Analyses of volume were adjusted for within-hospital (or within-surgeon) correlations in outcome with use of the generalized-estimating-equations modification of logistic regression.<sup>34</sup> We also analyzed results from the surgeons in the two highest-volume categories to examine potential variations among surgeons in outcome. We used a correlation-adjusted logistic-regression model to estimate the expected rate of events for each surgeon by adjusting for the surgeon's patients' ages and coexisting illnesses and by adjusting for hospital volume and surgeon volume, modeled as continuous variables. We tested for extrabinomial variation by comparing the observed and expected frequencies for each surgeon.<sup>35</sup> Testing for extrabinomial variation may identify additional surgeon-to-surgeon variations that cannot be explained by the factors used for adjustment in the logistic-regression model. We used the standardized deviations (z scores) of the observed frequencies from the expected frequencies for each surgeon to calculate the correlation between the outcomes and to characterize the degree to which individual surgeons could be identified as being associated with exceptionally high or low risk of adverse outcomes. All reported P values are two-tailed.

The project was reviewed and approved by the National Cancer Institute and by the Centers for Medicare and Medicaid Services. The National Institutes of Health has determined that analyses of the SEER-Medicare data base, with individual patient identifiers removed, are exempt from review by an institutional review board, according to the Code of Federal Regulations Title 45, Section 46.101.

**RESULTS**

We identified 11,522 men who had undergone radical prostatectomy between 1992 and 1996 (Table 1). Although the proportion of white patients treated in high-volume or very-high-volume hospitals was higher than that treated in low-volume or medium-volume hospitals, we found no evidence of substantial trends with respect to other patient characteristics. The patterns with respect to patient characteristics were similar for surgeon volume. Scores on the Romano-Charlson index were a strong and significant predictor of postoperative complications and late urinary complications (Table 2).

We found no relation between hospital volume and mortality associated with radical prostatectomy (Table 3). Increased hospital volume was related to decreased rates of postoperative and late urinary complications but not to decreased rates of long-term incontinence. Findings were similar with respect to the relation between surgeon volume and these outcomes (Table 4). Both hospital volume and surgeon volume remained significant predictors of postoperative and late urinary complications in analyses in which both these factors were included in the same model (data not shown).

Finally, we studied in detail the outcomes associated with the 159 surgeons in the two highest-volume categories, since the numbers of patients treated by each surgeon were sufficiently large to analyze surgeon-to-surgeon variations in outcome. These analyses revealed statistically significant variations among surgeons in

**TABLE 1. CHARACTERISTICS OF 11,522 MEN WHO UNDERWENT RADICAL PROSTATECTOMY BETWEEN 1992 AND 1996 IN RELATION TO THE VOLUME OF PROCEDURES PERFORMED AT THEIR HOSPITALS AND BY THEIR SURGEONS.\***

CHARACTERISTIC	HOSPITAL VOLUME			
	LOW (N=280)	MEDIUM (N=67)	HIGH (N=37)	VERY HIGH (N=19)
No. of patients	2736	2940	2899	2947
No. of patients per hospital (range)†	1-33	34-61	62-107	114-252
Mean age (yr)	70	70	70	70
Romano-Charlson comorbidity index (% of patients)‡				
0	75	78	80	81
1	21	19	17	16
≥2	5	3	3	3
White race (% of patients)	78	84	88	89
Stage III or IV cancer (% of patients)§	42	46	47	42

  

CHARACTERISTIC	SURGEON VOLUME			
	LOW (N=642)	MEDIUM (N=198)	HIGH (N=103)	VERY HIGH (N=56)
No. of patients	2662	2837	2555	2683
No. of patients per surgeon (range)¶	1-10	11-19	20-32	33-121
Mean age (yr)	70	70	70	71
Romano-Charlson comorbidity index (% of patients)‡				
0	77	76	77	81
1	19	20	19	16
≥2	4	4	4	3
White race (% of patients)	79	81	87	93
Stage III or IV cancer (% of patients)§	45	44	44	46

\*Because of rounding, not all percentages total 100.

†There were no hospitals with a volume of 108 to 113 patients. Assuming that 42 percent of patients undergoing prostatectomy are more than 65 years of age,<sup>25</sup> we project that these ranges correspond to total annual volumes of 1 to 16, 17 to 28, 29 to 50, and 51 to 120 prostatectomy procedures in hospitals with low, medium, high, and very high volumes, respectively.

‡The Romano-Charlson index is a weighted count of designated coexisting illnesses.

§Staging was not performed in 4 percent of the patients.

¶Assuming that 42 percent of patients undergoing prostatectomy are more than 65 years of age,<sup>25</sup> we project that these ranges correspond to total annual volumes of 1 to 4, 5 to 9, 10 to 15, and 16 to 58 prostatectomy procedures for surgeons with low, medium, high, and very high volumes, respectively.

their patients' rates of postoperative complications (P<0.001) and rates of late urinary complications (P<0.001) and long-term incontinence (P<0.001), defined in terms of symptoms and the use of treatment, after adjustment for age, the Romano-Charlson index, hospital volume, and surgeon volume.

The standardized deviations from the expected rates were calculated for each surgeon and showed clearly that some surgeons have patients with substantially worse rates of adverse events than can be predicted by the above-mentioned covariates or by residual chance

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**TABLE 2.** EFFECTS OF AGE AND CASE MIX ON OUTCOMES IN 11,522 MEN WHO UNDERWENT RADICAL PROSTATECTOMY BETWEEN 1992 AND 1996.

CHARACTERISTIC	SURGERY-RELATED DEATH		POSTOPERATIVE COMPLICATIONS	LATE URINARY COMPLICATIONS		LONG-TERM INCONTINENCE	
	30 DAYS	60 DAYS		SYMPTOMS OR PROCEDURES	MAJOR EVENTS	SYMPTOMS OR PROCEDURES	MAJOR EVENTS
Age (% of patients)							
65–69 yr	0.4	0.5	28	25	17	18	7
70–74 yr	0.5	0.6	31	25	17	19	7
≥75 yr	0.9	0.9	35	28	19	24	9
P value for trend	0.04	0.12	<0.001	0.34	0.17	<0.001	0.13
Romano–Charlson comorbidity index (% of patients)*							
0	0.3	0.4	28	25	16	18	7
1	0.8	1.0	34	27	18	20	7
≥2	1.6	1.6	43	31	19	21	7
P value for trend	<0.001	<0.001	<0.001	0.002	0.06	0.03	0.82

\*The Romano–Charlson index is a weighted count of designated coexisting illnesses.

**TABLE 3.** RELATION BETWEEN HOSPITAL VOLUME AND OUTCOMES IN 11,522 MEN WHO UNDERWENT RADICAL PROSTATECTOMY BETWEEN 1992 AND 1996.

OUTCOME	HOSPITAL VOLUME*				P VALUE	
	LOW (N=280)	MEDIUM (N=67)	HIGH (N=37)	VERY HIGH (N=19)	ADJUSTED FOR CLUSTERING†	ADJUSTED FOR CLUSTERING AND CASE MIX‡
	% of patients					
Surgery-related death						
30 days	0.5	0.5	0.5	0.5	0.92	0.81
60 days	0.6	0.6	0.6	0.5	0.94	0.68
Postoperative complications	32	31	30	27	0.02	0.03
Late urinary complications						
Symptoms or procedures	28	29	23	20	<0.001	<0.001
Major events	18	19	16	13	<0.001	<0.001
Long-term incontinence						
Symptoms or procedures	19	19	18	18	0.38	0.21
Major events	6.5	6.4	7.0	7.6	0.22	0.34

\*The volume categories correspond to 1 to 33 (low), 34 to 61 (medium), 62 to 107 (high), and 114 to 252 (very high) patients per hospital during the study period. There were no hospitals with a volume of 108 to 113 patients. Assuming that 42 percent of patients undergoing prostatectomy are more than 65 years of age,<sup>25</sup> we project that these ranges correspond to total annual volumes of 1 to 16, 17 to 28, 29 to 50, and 51 to 120 prostatectomy procedures per hospital, respectively.

†P values were adjusted only for within-hospital correlations.

‡P values were adjusted for both case mix and within-hospital correlations.

variation (which might result from the limited sample size for each surgeon): substantially more than 1 percent of the surgeons had patients with event rates above the 99th percentile in the predicted distribution of outcomes. Specifically, the patients of 12 (8 percent), 21 (13 percent), and 15 (9 percent) of these 159 surgeons had event rates for postoperative complications, late urinary complications, and long-term incontinence, respectively, that were above the predicted 99th percentile. Conversely, 4 (3 percent), 23 (14 percent), and 4 (3 percent) had exceptionally low rates, below the predicted first percentile. Furthermore, these differences in outcomes among individual surgeons' patients from the expected rates were correlated for the three morbidity-related outcomes. That is, surgeons who performed relatively poorly with respect

to the three morbidity-related outcomes. That is, surgeons who performed relatively poorly with respect

**TABLE 4.** RELATION BETWEEN SURGEON VOLUME AND OUTCOME AMONG 10,737 MEN WHO UNDERWENT RADICAL PROSTATECTOMY BETWEEN 1992 AND 1996.

OUTCOME	SURGEON VOLUME*				P VALUE	
	LOW (N=642)	MEDIUM (N=198)	HIGH (N=103)	VERY HIGH (N=56)	ADJUSTED FOR CLUSTERING†	ADJUSTED FOR CLUSTERING AND CASE MIX‡
	% of patients					
Surgery-related death						
30 days	0.4	0.5	0.5	0.5	0.71	0.74
60 days	0.5	0.5	0.6	0.6	0.74	0.59
Postoperative complications	32	31	30	26	0.008	<0.001
Late urinary complications						
Symptoms or procedures	28	26	27	20	0.003	0.001
Major events	19	18	17	14	0.01	0.01
Long-term incontinence						
Symptoms or procedures	20	20	19	16	0.08	0.04
Major events	7.3	7.2	6.7	6.6	0.82	0.34

\*The volume categories correspond to 1 to 10 (low), 11 to 19 (medium), 20 to 32 (high), and 33 to 121 (very high) patients per surgeon during the study period. Assuming that 42 percent of patients undergoing prostatectomy are more than 65 years of age,<sup>25</sup> we project that these ranges correspond to total annual volumes of 1 to 4, 5 to 9, 10 to 15, and 16 to 58 prostatectomy procedures per surgeon, respectively.

†P values were adjusted only for correlations among surgeons.

‡P values were adjusted both for case mix and for correlations among surgeons.

to postoperative complications also performed poorly with respect to late urinary complications (correlation coefficient, 0.21;  $P=0.009$ ), and vice versa. The corresponding correlations between rates of postoperative complications and incontinence and between rates of late urinary complications and incontinence were 0.14 ( $P=0.08$ ) and 0.35 ( $P<0.001$ ), respectively.

Finally, to evaluate the possibility that systematic variations in coding practice among hospitals may be responsible for exceptionally high or low event rates, we examined the number of hospitals at which the surgeons associated with exceptionally high rates of adverse events practiced. Approximately half of the 159 high-volume or very-high-volume surgeons (52 percent) practiced at a single hospital, 32 percent practiced at two hospitals, and 16 percent practiced at three or more hospitals. A similar distribution was apparent for the surgeons associated with exceptionally high rates of specific adverse outcomes: for example, 43 percent, 38 percent, and 19 percent of the 21 surgeons whose patients had very high rates of late urinary complications practiced at one, two, or three or more hospitals, respectively. These 21 surgeons performed their procedures at different hospitals, with the exception of 2 surgeons who worked at the same hospital. A similar pattern was obtained for the other two outcomes.

## DISCUSSION

The National Cancer Policy Board of the Institute of Medicine has drawn attention to the possibility of

substantial variations in both access to high-quality care for cancer and the quality of the care itself.<sup>36</sup> That report was influenced by numerous studies that showed that increased hospital volume predicts decreased mortality after definitive cancer surgery.<sup>1-15</sup> The trends reported in these studies are broadly consistent and show dramatic differences in mortality according to hospital volume among patients undergoing relatively rare, high-risk surgical procedures but much smaller effects among those undergoing lower-risk, more common procedures. In fact the Leapfrog Group, an organization of large companies and health care providers concerned about the safety and value of health care, has advocated evidence-based referral of patients to high-volume hospitals for procedures that are associated with a high rate of death.<sup>37</sup> Our view is that the apparently small effect of hospital volume on the rate of death after common procedures may mask more profound differences in outcome with respect to quality-of-life end points that are of great importance to patients.

Even within the category of high-volume surgeons, we found substantial variation in outcome among individual surgeons after adjustment for hospital volume, case mix, and the random variation that is inevitable within relatively small groups of patients. The evidence suggests that these results reflect genuine variations in surgical performance. This conclusion is supported by our observation that surgeons whose patients had high rates of complications in one category of outcome

tended to have patients with high rates of complications in the other categories as well. Consequently, initiatives (such as those of the Leapfrog Group) that recommend the use of the volume of procedures as a criterion for the referral of patients to health care providers may help improve some aspects of the quality of care. However, there will still be opportunities to improve the quality of care, even in high-volume institutions.

Our analyses support the validity of most of our measures of volume and outcome. Our measure of long-term incontinence, however, had poor sensitivity for detecting this outcome. As a consequence of the resulting loss of statistical power, we cannot rule out the possibility that hospital volume and surgeon volume are also predictors of incontinence. Another limitation of our methods is that the variations in outcome that we observed may in part reflect differences in case mix among hospitals and surgeons. The extent of coexisting conditions, as represented by the Romano–Charlson index, and (to a lesser extent) age were predictors of major adverse events, in addition to death after prostatectomy (Table 2). The fact that these factors were evenly distributed among the four quartiles of hospital volume and surgeon volume gives some reassurance that selection bias did not affect our results. However, these are crude and incomplete measures of risk, and therefore we cannot rule out the possibility that the variations we observed may be due to inadequate adjustment for risk factors, especially in the analysis of individual surgeons.

An important factor that can influence the quality of surgical care is the availability of ongoing feedback about adverse outcomes to surgical teams and individual surgeons; such feedback may stimulate modifications of technique in the attempt to reduce the occurrence of adverse outcomes in the future. The principal adverse events, such as death related to surgery and the most life-threatening in-hospital events, are immediately apparent to the surgical team. Late events that are not life-threatening but that affect the patient's quality of life may be less readily apparent and, indeed, may not be observed by surgeons at all, so that the feedback that might prompt a modification to surgical technique is greatly diminished. Our results suggest the need for more careful scrutiny of adverse outcomes so as to reduce the burden of suffering among patients who undergo surgery for prostate cancer. The existence of substantial variations in outcomes should stimulate more active educational efforts by professional societies to optimize the quality of surgical care.

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