Operative duration and short term morbidity and mortality following radical cystectomy with urinary diversion

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Introduction: *To elucidate the association between operative duration (OD) and postoperative complications, which has been poorly studied in radical cystectomy. We hypothesize an increase in morbidity in radical cystectomy cases which have a longer OD.*

Materials and methods: *Data from the National Surgical Quality Improvement Program (NSQIP) between the years 2012 and 2018 were reviewed for radical cystectomy with ileal conduit urinary diversion or continent diversion. Total operative time was divided into deciles and stratified comparisons were made using univariable and multivariable analysis.*

Results: *A total of 11,128 patients were examined. OD by minutes was stratified into the following deciles: 90-201, 202-237, 238-269, 270-299, 300-330, 331-361, 362-397, 398-442, 443-508, > 508. Operative times were shorter for patients with advanced age ($p < 0.001$), male gender ($p < 0.001$), low body mass index (BMI) ($p < 0.001$), bleeding diathesis ($p = 0.019$), COPD ($p = 0.004$), and advanced ASA class ($p < 0.001$). Complications significantly associated with prolonged OD included surgical site infection, urinary tract infection, sepsis/septic shock, renal failure and venous thromboembolism. On multivariate analysis, factors predictive of perioperative morbidity included presence of bleeding disorder (OR 1.70, 95% confidence intervals (CI) 1.37-2.12, $p < 0.001$), ASA Class IV-V compared to I-II (OR 2.26, 95% CI 1.89-2.72, $p < 0.001$), and prolonged operative time (tenth decile OR 3.05, 95% CI 2.55-3.66, ninth decile OR 2.11 95% CI 1.77-2.50, third decile OR 1.31, 95% CI 1.11-1.56, second decile OR 1.02, 95% CI 0.86-1.21 compared to first decile, $p < 0.001$)*

Conclusion: *OD is an independent predictor of post-operative morbidity in patients undergoing radical cystectomy, even when adjusting for patient specific factors. Those patients within the longest decile had over 3-fold increase in the risk of morbidity compared to those with shorter OD.*

Key Words: operative duration, radical cystectomy, morbidity, complications

Introduction

Bladder cancer is the second most common urologic malignancy, with an estimate of over 81,000 new cases in 2020.[1] Bladder cancer has a high mortality rate, with an estimated 17,980 deaths expected in 2020. Radical cystectomy (RC) with pelvic lymphadenectomy is considered the gold-standard for treating patients with non-metastatic muscle-invasive bladder cancer, conferring improvement in long term survival.[2] Unfortunately, this procedure carries significant morbidity, with studies reporting complication rates ranging from 32%-64%.[3-5] Patients undergoing RC often experience a high rate of complication and readmission in the setting of significant comorbid illnesses associated with the disease.

Bladder cancer also is associated with a considerable financial burden.[6] Due to the health and financial

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burdens associated with RC, there have been many efforts to identify risk factors and causation of complications to reduce the morbidity associated with this procedure.[7] Up to 26% of readmissions may be modifiable, demonstrating the potential to decrease burden through improvement in treatment algorithms and perioperative pathways.[8] One study found, through an outside consultant, that the single institution lost an estimated $6,000,000 annually due to complications.[9] The same study proclaimed an opportunity to relatively "easily" reduce these costs by 30% to 40%.

Operative duration (OD) has also been associated with adverse outcomes in other urological surgeries and in other surgical disciplines.[10-13] Previous work has shown increased OD is an independent predictor of morbidity in urologic surgery. For both minimally invasive prostatectomy and partial nephrectomy, patients in the longest decile of OD were 2.3 and 3.7 times more likely to have postoperative complications, respectively. While determinants of OD in cystectomy have been investigated,[14] a dearth of data exists concerning the effect of OD on perioperative outcomes. We hypothesize longer OD is associated with increased complications in patients undergoing radical cystectomy.

Materials and methods

Data from the public use files produced by the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) between the years 2012 and 2018 were reviewed for cases with radical cystectomy as the primary Current Procedural (CPT) medical code. The CPT codes used are as follows: 51590/51595 (collectively referred to as radical cystectomy with ileal or sigmoid conduit) and 51596 (radical cystectomy with continent diversions). Patients who underwent continent cutaneous or other diversion techniques were excluded. OD is defined as the time from first incision until incision closure and bandage placement. Cases were excluded if the total operation time was less than 90 minutes. Additionally, cases were excluded if they were missing data on sex, height, weight, or ASA class. NSQIP indicates age of 90 or older as "90+", therefore age of 90 was imputed for these cases. A morbidity was defined as any of the following 30-day complications: mortality, superficial incisional surgical site infection (SSI), deep incisional SSI, organ/space SSI, wound dehiscence, pneumonia, bleeding transfusion, urinary tract infection (UTI), unplanned intubation, on ventilator for more than 48 hours, sepsis, septic shock, acute renal failure, progressive renal insufficiency, pulmonary embolism, deep vein thrombosis (DVT) or thrombophlebitis, cardiac arrest requiring CPR, myocardial infarction, and stroke with neurological deficit or cerebrovascular accident (CVA). Smoker is defined as current smoker within 1 year.

Total operative time was divided into deciles and stratified comparisons were made. Deciles were utilized given the large dataset, to ensure that intervals were properly narrowed to precisely capture inflection points within the data. For categorical variables, frequencies and column percentages were reported and p values were calculated using Pearson's Chi-Square test, as appropriate. Continuous variables were tested for normality using Shapiro-Wilk normality test and histograms. For normally distributed continuous variables, means and standard deviations (SD) were reported and p values were calculated using one-way ANOVA; otherwise, medians and first and third quartiles [Q1, Q3] were reported and p values were calculated using Kruskal-Wallis tests.

Initial variables utilized for multivariable analysis included age, sex, body mass index (BMI), chronic obstructive pulmonary disease (COPD), patient functional status, wound disruption, preoperative white blood cell count (WBC), surgeon specialty, American Society of Anesthesiologists (ASA) class, preoperative infection, type of diversion. After fitting the stepwise model with the Akaike information criteria, the significant predictor variables were reduced to the following: age, sex, functional status, ASA class, and wound class.

Statistical significance was set at p value < 0.05. All analyses were conducted using the statistical programming language R, version 3.6.1 (R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 11,128 patients met inclusion criteria. Cases were stratified by OD decile. The median operative time was 5.5 hours. Ten percent of cases lasted longer than 8.5 hours. Factors associated with prolong operative duration include female gender and elevated BMI ($p < 0.001$). Operative times for patients with advanced age ($p < 0.001$), bleeding diathesis ($p = 0.019$), COPD ($p = 0.004$), and advanced ASA class ($p < 0.001$) were relatively shorter. Preoperative laboratory values, including serum white blood cell and platelet count, hemoglobin, hematocrit, sodium and creatinine levels, were investigated relative to OD. While elevated serum creatinine ($p = 0.002$) was associated with shorter OD, the other values were not

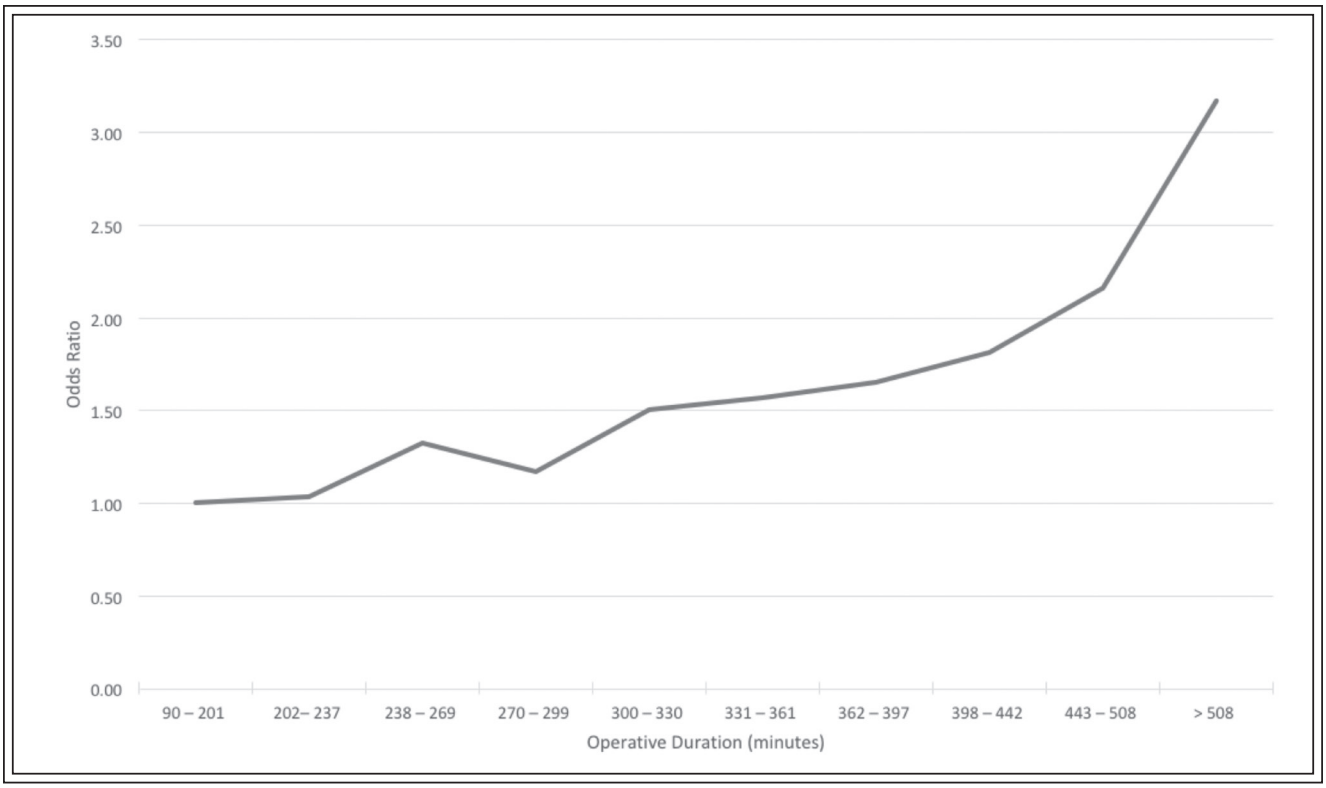

Figure 1. Odds ratio of morbidity relative to operative duration by deciles.

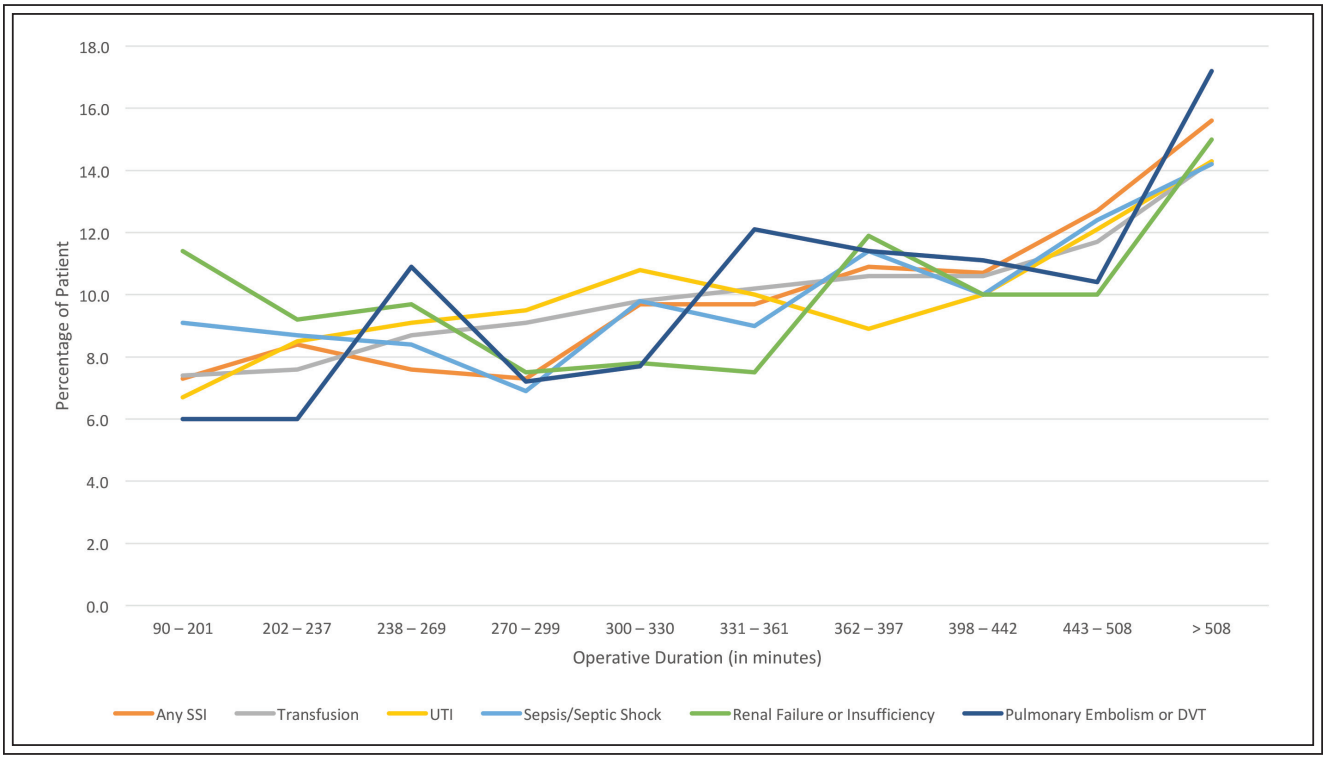

Figure 2. Complications by operative duration in decile.

statistically significant. On stepwise multivariable regression analysis female gender, high BMI and lack of functional independence was associated with longer OR times, while advanced age and ASA class were associated with shorter operative times.

Perioperative morbidity and mortality were then analyzed based on OD. The odds ratio of postoperative morbidity relative to OD decile can be seen in Figure 1. Thirty day mortality was low and similar among deciles. Complications significantly associated with prolong OD included SSI, UTI, sepsis/septic shock, renal failure or insufficiency, and PE/DVT, Figure 2. The rate of transfusion increased with increasing OD, with 7.4% of patients being transfused in the first decile and 14.3% in the last decile ($p < 0.001$). On multivariate analysis, Table 1, factors most notably predictive of perioperative morbidity included presence of bleeding disorder (OR 1.71, 95% confidence intervals (CI) 1.37-2.12, $p < 0.001$), ASA Class IV-V compared to I-II (OR 2.30, 95% CI 1.92-2.77, $p < 0.001$), and OD. Prolonged OD was statistically significantly associated with perioperative morbidity starting at the 5th decile (OR 1.49, $p < 0.001$), extending to the 10th decile (OR 3.05, $p < 0.001$; Table 1).

Lastly, we compared urinary diversion techniques (ileal conduit vs. continent diversion) with regards to operative time and perioperative morbidity, Table 2. Continent diversion was associated with an additional median 54 minutes of operative time compared to ileal conduit formation ($p < 0.001$). This was also associated with a higher rate of 30-day morbidity compared to ileal conduit reconstruction (56.5 vs. 52.6%, $p = 0.001$). Rates of postoperative UTI (13.4% vs. 7.5%, $p = 0.005$), surgical site infection (16.5% vs. 12.4%, $p < 0.001$),

TABLE 1. **Effect of operation duration decile on morbidity adjusted for predictors**

Parameter	Odds ratio	95% confidence interval	p value
Intercept	0.56	(0.40, 0.79)	< 0.001
CPT code			
51590	1.00	Reference	Reference
51595	0.99	(0.89, 1.09)	0.7863
51596	1.25	(1.09, 1.43)	< 0.001
Age (in years)	1.01	(1.00, 1.01)	< 0.001
Sex			
Female	1.00	Reference	Reference
Male	0.57	(0.51, 0.63)	< 0.001
COPD	1.27	(1.09, 1.48)	0.002
Bleeding disorder	1.71	(1.37, 2.12)	< 0.001
BUN	1.02	(1.01, 1.02)	< 0.001
ASA class			
I-II	1.00	Reference	Reference
III	1.39	(1.27, 1.53)	< 0.001
IV-V	2.3	(1.92, 2.77)	< 0.001
Operation duration			
90-201 minutes	1.00	Reference	Reference
202-237 minutes	1.02	(0.86, 1.21)	0.8394
238-269 minutes	1.31	(1.11, 1.56)	0.0018
270-299 minutes	1.17	(0.99, 1.38)	0.0704
300-330 minutes	1.49	(1.25, 1.77)	< 0.001
331-361 minutes	1.56	(1.31, 1.85)	< 0.001
362-397 minutes	1.63	(1.37, 1.93)	< 0.001
398-442 minutes	1.78	(1.50, 2.11)	< 0.001
443-508 minutes	2.11	(1.77, 2.50)	< 0.001
> 508 minutes	3.05	(2.55, 3.66)	< 0.001

COPD = chronic obstructive pulmonary disease; ASA = American Society of Anesthesiologists

TABLE 2. **Operation duration deciles by radical cystectomy with ileal conduit versus radical cystectomy with continent diversion**

	CPT code		
	RC with conduit	**RC with continent diversion**	**p value**
Operation duration			< 0.001
90-200 minutes	1031 (91.3)	98 (8.7)	
201-236 minutes	975 (86.4)	154 (13.6)	
237-270 minutes	942 (86.9)	142 (13.1)	
271-300 minutes	987 (87.9)	136 (12.1)	
301-332 minutes	967 (86.0)	158 (14.0)	
333-364 minutes	923 (84.5)	169 (15.5)	
365-400 minutes	905 (81.0)	212 (19.0)	
401-445 minutes	879 (81.0)	226 (20.5)	
446-512 minutes	852 (75.9)	271 (24.1	
> 512 minutes	753 (68.4)	348 (31.6)	
Intercept (median 389.2 minutes for all, 95% CI 383.8, 394.6)	0.0 (reference)	+53.7 (+47.7, +59.6)	< 0.001
30-day morbidity			0.001
No	4397 (47.7)	834 (43.6)	
Yes	4817 (52.3)	1080 (56.4)	

RC = radical cystectomy

and postoperative sepsis (15.3 vs. 10.8%, $p < 0.001$) were all higher in the continent diversion group as compared to incontinent diversions. Rates of death within 30 days (1.7% vs. 1.9%, $p = 0.602$), intra or postoperative transfusion (34.0% vs. 35.9%, $p = 0.098$), and pulmonary embolism or deep vein thrombosis requiring therapy (4.6% vs. 3.8%, $p = 0.108$) were not statistically different between the groups.

Discussion

These data indicate that 30-day morbidity was significantly associated with prolonged OD. Starting at the fifth decile (300 minutes) there was a significant increase in risk of perioperative morbidity (OR 1.49, $p < 0.001$). This increased to a 3.2-fold increase for patients in the highest decile of OD. When looking at morbidity, the top two deciles accounted for over 25% of all complications. While other studies have investigated perioperative risk factors associated with morbidity after RC, to our knowledge this is the first study assessing the association of OD with 30-day perioperative morbidity.

The association between increased OD and postoperative complications has been well established in other surgical fields, including general surgery, orthopedics, and otolaryngology.[15-17] This phenomenon has been less robustly studied in urologic procedures. Studies examining minimally invasive procedures, including partial nephrectomy and prostatectomy, have found OD to be an independent predictor for morbidity, even when adjusting for preoperative factors.[18,19] Similar findings have been described in ureteroscopy which had a complication afterward lasted an average of 11 minutes longer than those without complication ($p < 0.0001$).[20] When focusing on radical cystectomy, a multi-center study assessing outcomes from over 2,300 patients undergoing radial cystectomy across a 6-year period found that operative time greater than 6 hours was associated with increased postoperative complications within 30 days of surgery (RR 1.30, 95% CI 1.20-1.40, $p < 0.0001$).[21] Our results show a similar association in over 11,000 patients undergoing radical cystectomy in the NSQIP database, though our findings suggest a statistically significant increase in complication rates starting at 4+ hours of operative time, likely related to increased power from a larger sample size.

There are a variety of factors that contribute to long OD. Previous research has shown that meticulous technique, case complexity, patient characteristics, trainee involvement, intraoperative communication,

and intraoperative complications all contribute to case duration.[10,12,22] Radical cystectomy is a relatively long urologic procedure, but it remains unclear as to what factors directly impact OD. Filson et al examined factors associated with OD of RC found that type of diversion played the largest role in OD.[14] [14] Their results agreed with our own, showing a similar median OD, and a significant increase in OD in female patients, with decreasing OD in the elderly. Continent diversion added an average of 35 minutes to a case when compared to ileal conduit. The difference in continent diversion times seen between our results and those of Filson et al is most likely due to a difference in sample size, as they included significantly less patients. Perioperative anesthetic procedures, such as epidural or arterial line placement, added 47 minutes when compared to those without ($p < 0.001$). Extended lymph node dissection templates also increased the length of procedure. Patient factors, such as age (-2 minutes/year of age, $p < 0.001$) and sex (females 32.3 minutes longer, $p < 0.001$) also significantly impacted OD. These authors also found that OD was longer in academic centers relative to community centers and shorter in more high-volume surgeons. This study did not examine the association of these factors with postoperative complications.

Our results indicate shorter operative duration in higher-risk cases. Our study assessed the ASA physical status classification system among this cohort. Within this system, class IV patients are described as having severe systemic disease that is a constant threat to life, while class V are moribund patients who are not expected to survive without the operation.[23] Our analysis showed cases with ASA class IV or V rating lasted an average of 15.5 minutes less when compared to class I-II ($p = 0.0023$), though this small difference is unlikely to make a significant difference on morbidity. Our results are consistent with multiple previously published studies, which showed decreasing operative durations in the ASA classification above III.[24,25] Perhaps the decreased OD in these cases results from surgeons progressing more quickly in these higher-risk patients.

Our data confirm longer OD with continent diversion reconstruction compared with ileal conduit urinary diversion (+54 min). This raises the question, are increased complication rates caused by the difference in technique or the increased OD? In addition to increased OD for those getting a continent diversion, other factors must also be considered. An important consideration includes the differences in patient selection, as candidates for continent diversion are younger, with less comorbid conditions, on average. Multiple studies have shown that when accounting for baseline demographic differences, complication rates across the techniques are equal.[26,27] Both studies utilized propensity score matching and followed postoperative complications up to 90 days after surgery, with no differences in morbidity. The results from these studies suggest that the procedures themselves are not the cause of the increased complication rate, but the increased OD may be the cause. Our results include an analysis across different CPT codes, which showed a statistically significant, moderate increase in OD and morbidity for the CPT code 51596 for continent diversion, (OR 1.25, 95% CI 1.09-1.43, $p < 0.001$), relative to CPT code 51590 which is for ileal conduit. Further investigation is required to directly compare complication rates for continent diversion and ileal conduit cases with similar OD.

Operative time may also have a large impact on cost. It has been estimated that a high complexity case may cost as much as $80 per minute.[28] Examination of the increased surgical costs associated with OD has been performed with other urologic procedures. For example, a study of minimally invasive partial nephrectomy cost has been done to include preoperative and perioperative variables. The results again showed an association between increased OD and increased cost, with multivariable analysis showing that OD increases direct cost by $680 per 30-minute increase ($p < 0.001$).[29] The study also highlights how expensive individual complications can be. For example, blood loss greater than 250 cc's increases cost by an average of $800, and blood transfusions increasing cost by $3,700. Similar assessment of cost has been done for prostatectomy. For this procedure, each 30 minutes increase in OD increased cost by $410.[30] On average, any postoperative complication increased direct cost by $5,397, and transfusion by $2,900, showing that cases lasting longer than 4.5 hours were $3,000 dollars more expensive than the average. Less robust data exists for radical cystectomy. One study showed an average cost of $11,728 due to complications in the immediate post-operative period after radical cystectomy.[31] Another study found that a single complication after radical cystectomy increase the median total hospital charges by $15,000 and increased the length of stay by 4 days.[32] With our results showing the increased risk of complications associated with increased OD, and previous work discussed here, prolonged OD provides an interesting target for improvement in value of care. Our study suggests that the costs associated with RC may be decreased both by decreasing the operative duration and the complications associated with prolonged OD.

Beyond cost, blood loss leading to transfusions also significantly alters oncologic outcomes. Our results showed a significant increase in transfusion rate with increasing OD, which may have impacted oncologic outcomes. While debate remains around the topic, perioperative blood transfusions have been associated with a reduction in recurrence free survival by 12%, cancer specific survival by 29%, and overall survival 27% in a meta-analysis of eight studies.[33]

This study is not without limitations. Inherent limitations exist with the NSQIP database we utilized for the study. Previous work in multiple other disciplines has shown a lack of accuracy in reporting complications.[34,35] Despite this, NSQIP remains an efficient way to study procedures on a large scale within urology, and while misclassifications in complications may exist, the rate at which any postoperative complication occurs likely remains accurate. While the data shows an association between increased OD and postoperative complications, there are many possible confounding factors that may be the cause of this association as we were unable to control for surgeon experience, ERAS protocol implementation, and oncologic characteristics such as stage which may impact OD and perioperative outcomes. Cancer specific outcomes, and patient specific quality of life outcomes were unable to be measured within this study.

Due to the nature of CPT codes, and their lack of differentiation between robotic and open RC, we were unable to reliably differentiate which procedures were performed robotically compared to open. There may be differences across approach, including both OD and complication rates, which we were unable to identify. A recent meta-analysis has confirmed this to be the case, showing OD to be longer in the robot-assisted group (mean difference 68.51 minutes, 95% CI 30.55-105.48) when compared to open.[36] This study found no difference in major complications, defined as Clavien III-V (RR 1.06, 95% CI 0.75-1.49). Similar analysis in this cohort would have been useful. Despite our limitations, we feel this study will help begin the discussion and be hypothesis generating regarding operative durations and its effects on outcomes within urology.

Conclusion

RC operative duration of 300 minutes or longer shows a significantly increased risk of complications, while OD of 508 minutes or longer confers a greater than 3-fold increase in odds of complication, when compared to shorter OD. Longer OD is likely an independent risk factor for postoperative complications, which persists when adjusting for patients' specific characteristics and diversion type. OD remains a potential target for improving value of care for patients, and potential decreases in health care costs via decreased morbidity and decreased operative room expenditures. □

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