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Factors that Influence Selection of Urinary Diversion among Bladder Cancer Patients in Three Community-Based Integrated Health Care Systems

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Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Abstract

Objectives: To assess the relative contributions of patient and surgeon factors for predicting selection of ileal conduit (IC), neobladder (NB), or continent pouch (CP) urinary diversions (UD) for patients diagnosed with muscle-invasive/high-risk non-muscle invasive bladder cancer. This information is needed to enhance research comparing cancer survivors' outcomes across different surgical treatment options.

Methods: Bladder cancer patients age ≥ 21 years with cystectomy/UD performed from 1/2010 to 6/2015 in three Kaiser Permanente regions were included. All patient and surgeon data were obtained from electronic health records. A mixed effects logistic regression model was used treating surgeon as a random effect and region as a fixed effect.

Results: Of 991 eligible patients, 794 (80%) received IC. 169 surgeons performed the surgeries and accounted for a sizeable proportion of the variability in patient receipt of UD (ICC=.26). The multilevel model with only patient factors showed good fit (AUC=.93, Hosmer-Lemeshow test $p=.44$), and older age, female sex, eGFR<45, 4+ comorbidity index score, and stage III/IV tumors were associated with higher odds of receiving an IC vs. NB/CP. However, including surgeon factors (annual cystectomy volume, specialty training, clinical tenure) had no association ($p=.29$).

Conclusions: In this community setting, patient factors were major predictors of UD received. Surgeons also played a substantial role, yet clinical training and experience were not major predictors. Surgeon factors such as beliefs about UD options and outcomes should be explored.

Keywords

bladder cancer; urinary diversion; ileal conduit; neobladder; cystectomy; decision-making

Introduction

Each year, approximately 10,000 patients with bladder cancer in the U.S. undergo radical cystectomy (bladder removal) [1]. While radical cystectomy is clearly associated with improved patient survival, choosing between different urinary diversion (UD) options is often not straightforward [2, 3].

Ileal conduits are the most common UD, accounting for approximately 80% of diversions in the U.S [4]. Neobladder and colon pouch diversions aim to retain urinary continence, avoid external appliances, and minimize body-altering effects. However, research has not consistently demonstrated that neobladders and colon pouches lead to better outcomes in bladder cancer survivors [2, 5].

The mixed evidence on outcomes associated with different UD types illustrates a common challenge of observational, comparative effectiveness studies in surgical oncology [6]. The strength of evidence of treatment effects from such studies is often hampered by selection bias and confounding due to unmeasured variables [7, 8]; yet conducting clinical trials to randomly assign patients to one treatment arm or another is often not feasible in real-world clinical settings. A possible solution to this limitation is creation of models predicting treatment assignment using data from electronic health records (EHR) [8].

Therefore, we assessed the fit of a parsimonious model built using EHR data for predicting assignment of UD (ileal conduit, neobladder, or continent pouch) for patients diagnosed with muscle-invasive/high-risk non-muscle invasive bladder cancer in a community setting. Specifically, we examined the association of patient and surgeon characteristics relevant to UD selection in a large cohort of bladder cancer patients treated with cystectomy and UD from 2010 through 2015 in three Kaiser Permanente regions. Our study was part of a larger National Cancer Institute-funded study that followed bladder cancer survivors for two years after cystectomy to compare costs, complications, and quality of life issues associated with each option.

Materials and Methods

Study Population

The Bladder Cancer Quality of Life Study included 1,063 patients (age ≥ 21 years) who received a cystectomy with urinary diversion (ileal conduit, neobladder, or continent pouch) for bladder cancer between January 2010 and June 2015, and who were members of one of three integrated health care systems. Together the systems serve about 8.5 million members. We had complete data on 991 patients for this analysis. This study was approved by the Institutional Review Boards of the three systems.

Data Collection

Patient characteristics and outcomes were obtained using distributed programs that accessed the clinical and administrative data systems at each site. Site-specific data were extracted into a study-specific standardized data model to facilitate analyses, building on the data infrastructure developed through the NCI-supported Cancer Research Network [9].

Age at surgery, sex, race, ethnicity, and body mass index (BMI) within 6 months before surgery were obtained from clinical and administrative data sources. AJCC stage at bladder cancer diagnosis (0a, 0is, I, II, III, IV), tumor grade (low, moderate, high), neoadjuvant therapy, and prior history of pelvic cancer were obtained from institutional cancer registries and chart reviews. The revised Charlson-Deyo comorbidity index was calculated for the 12 months prior to cystectomy using diagnosis and procedure codes for the relevant conditions [10]. Because all patients were diagnosed with bladder cancer, the minimum comorbidity score was 2. Time from bladder cancer diagnosis to surgery was calculated in months.

Estimated glomerular filtration rate (eGFR), albumin, and bilirubin were obtained from electronic laboratory data sources. eGFR was classified as follows: <45 mL/min/1.73m² (moderately to severely reduced kidney function), 45–60 (moderately reduced), 61–90 (mildly reduced), and >90 (normal). An overall status for liver impairment at time of cystectomy was created based on diagnosis of cirrhosis and/or abnormal albumin or bilirubin liver function tests (LFT) within 12 weeks prior to cystectomy.

Cystectomies were identified from electronic medical records and billing systems using common procedure codes (CPT), International Classification of Diseases codes (ICD), and other billing-related codes. We reviewed each patient's medical record and operative report to document the following: bladder cancer diagnosis date, complete cystectomy performed,

type of diversion received, and surgeon of record. Due to the small number of continent pouch surgeries, we combined neobladder and continent pouch diversions, and thus created a binary urinary diversion type variable (ileal conduit vs. neobladder or continent pouch).

Surgeons' annual cystectomy volume, years since medical school graduation, years employed at KP, and specialty training (fellowship) were obtained from provider electronic data sources, physician directories, and websites. Surgeon volume was calculated as total number of UD surgeries/tenure years at KP across all study calendar years. All surgeons performed at least one ileal conduit surgery during the study period, and a subset also performed neobladder and/or continent pouch surgery. For analytic purposes, surgeons were placed into two groups: those who performed only ileal conduits during the study period, and those who also performed neobladder and/or continent pouch procedures.

Statistical Analysis

Our analysis examined the association of patient and surgeon factors with UD type. To account for clustering of patients within surgeons within regions, we used hierarchical generalized linear modeling (HGLM) to identify patient characteristics associated with type of diversion [11–13]. HGLM allows for simultaneous analysis across multiple levels (e.g., patient and surgeon levels). Because the primary outcome is binary (receipt of ileal conduit vs neobladder/continent pouch), we used a model with a logit link and binomial distribution. We modeled surgeon as a random effect and KP region as a fixed effect. We also included time in months from date of bladder cancer diagnosis to date of surgery as a person-level covariate. We performed an unconditional model (i.e., model that estimates only the random intercept and adjusting for region) to calculate the intraclass correlation coefficient (ICC), which quantifies the variation in the outcome (receipt of ileal conduit vs neobladder/continent pouch) that is attributable to the surgeon effect. We evaluated overall model fit using the area under the curve (AUC) [14] as a measure of discrimination (ability to differentiate those predicted to choose ileal conduit vs. neobladder/continent pouch), and the Hosmer-Lemeshow test [14] using deciles as a measure of calibration (degree to which model matched predicted and observed risk of choosing ileal conduit vs. neobladder/continent pouch). We considered a model with an AUC of .80 and a non-significant Hosmer-Lemeshow test [15] as evidence of good discrimination and calibration, respectively, and thus good model fit.

Patient and surgeon factors were selected *a priori*, and thus all variables were retained in the multivariable models. We included patient-level predictor variables in a multivariable model to determine the factors that were independently associated with receiving neobladder/continent pouch compared to ileal conduit surgery. Next, we tested whether adding surgeon characteristics as predictors improved model fit with the Likelihood Ratio (LR) test, thus potentially further explaining reasons for receiving neobladder/continent pouch as opposed to ileal conduit. We evaluated all inferential analyses with a two-tailed alpha level of .05, and reported odds ratios (OR) and associated 95% confidence intervals (CI).

In addition, we calculated the relative importance of each predictor using the adequacy index [16, 17]. The adequacy index is calculated by dividing the model likelihood ratio (LR) χ^2 for a model that includes only the predictor of interest by the model LR χ^2 that includes all

predictors of interest. Hence, the adequacy represents the proportion of information that could be captured by a single predictor compared to the multivariable model, with higher values indicating greater importance.

All analyses were performed with SAS v.9.3 and Stata v.13.1 [18].

Results

Of the 991 patients in this analysis, 794 (80%) received an ileal conduit, and 761 (77%) were non-Hispanic white. Ileal conduit patients were older (mean age 72 vs. 62 years); more likely female, 24% (192) vs. 16% (31); more likely diagnosed with stage III/IV bladder cancer, 42% (337) vs. 26% (337); and had higher Charlson-Deyo comorbidity scores (median 4 vs. 3) than neobladder/continent pouch patients (Table 1).

A total of 169 unique surgeons performed the UD surgeries on patients in the study cohort, of whom 99 (59%) performed only an ileal conduit and 70 (41%) performed a combination of surgeries including ileal conduit, neobladder, and continent pouch (Table 2). The mean UD volume for surgeons who performed neobladder or continent pouch diversions was more than double that of surgeons who only performed ileal conduits (2.1 vs. 0.8 surgeries per year employed at KP, respectively). These surgeons were also more recently trained (mean 15.3 years vs. 17.0 years since medical school graduation, respectively) and more likely to have completed a clinical fellowship: 40% (28) vs. 21% (21), respectively. Finally, a larger proportion of surgeons who performed neobladder/continent pouch diversions had been employed at KP longer than 5 years, compared to surgeons who only performed ileal conduit diversions: 80% (56) vs. 75% (74).

In the multilevel model accounting for the clustering of surgeons, we found that surgeon effects accounted for a sizable proportion of the variability in UD type received ($ICC=.26$). The model with patient factors showed good fit as evidenced by good discrimination ($AUC=.93$) and calibration (Hosmer-Lemeshow test $p=.44$). However, adding cystectomy volume, training, and tenure of the surgeon to the model did not improve model fit ($LR \chi^2(8)=9.7$, $p=.29$), indicating that these measured surgeon factors were not associated with selection of UD type. Thus, we evaluated the model coefficients for the model that included only patient factors.

Older age ($OR=4.31$; 95% CI: 3.14, 5.91), female sex ($OR=2.39$; 95% CI: 1.32, 4.35), kidney function $<45 \text{ mL/min/1.73 m}^2$ ($OR=4.30$; 95% CI: 1.38, 13.36), 4+ comorbidities ($OR=2.32$; 95% CI: 1.34, 4.01), and stage IV tumor ($OR=4.00$; 95% CI: 1.97, 8.09) were associated with higher odds of receiving an ileal conduit vs. a continent diversion (Table 3). No significant associations were observed with race, Hispanic ethnicity, liver dysfunction, history of pelvic cancer, or time from diagnosis to surgery. As for relative importance based on the adequacy index, the most informative predictor was age (.93), followed by Charlson-Deyo score (.46) and kidney function (.40).

Comment

A parsimonious model using readily available patient factors (age, comorbidity score and kidney function) explained the majority of variation in type of UD received in this large, community-based cohort of bladder cancer patients. Our findings are consistent with clinical recommendations for ileal conduit compared with continent diversions, which include older age, greater number of comorbidities, lower kidney function, and advanced stage tumors [19–21]. Interestingly, and to our knowledge not previously reported, we also found a fairly large surgeon effect in predicting UD type; however, the specific surgeon characteristics we included in the model did not predict type of UD received above and beyond that predicted by patient-level characteristics dictated by clinical recommendations for this complex surgery.

Surgeons' contributions to type of UD received might be explained by other more nuanced factors, including their clinical judgment about options for patients. Moreover, our approach could not account for how shared decision-making between patients and surgeons may have influenced UD choice. Some surgeons may engage in shared decision-making more than others, but it is by its nature a collaborative process that involves both patients and surgeons. Further research investigating these crucial aspects of decision-making, which are best assessed through self-report or observation, could help illuminate our findings.

Our findings are consistent with those of a 2015 study of 828 cystectomy patients conducted at a large cancer center that examined patient- and disease-specific factors in relation to UD type receipt [22]. However, we found that women may be less likely to receive a neobladder than men, even after controlling for other clinical factors relevant to UD type, while the other study reported no difference in receipt of UD type by sex. Historically, women were considered a high-risk group for continent diversions, specifically neobladders, compared with men due to differences in lower urinary tract anatomy when re-attaching the urethra to the neobladder [23]. However, more recent data suggest that women can also be good candidates for neobladder [24, 25]. Studies are needed to explore this gender disparity, and whether it holds across practice settings [26].

Our results suggest that the receipt of an ileal conduit compared with a neobladder or continent pouch is a complicated decision driven by both patient and physician factors. While there is a subgroup of patients who are not good candidates for continent diversions due to clinical and/or medical factors (e.g., poor kidney function, late-stage disease, or concern about metastasis), other less apparent factors likely play a role in the type of UD received. For example, older bladder cancer patients with higher likelihood of comorbid conditions may be seen as not having the vigor to withstand retraining a neobladder or maintaining a continent pouch. Further, their surgeons may be concerned about placing a higher recovery burden on these patients. This is, ideally, a joint decision by patients and their surgeons. Consistent with this, Berry and colleagues reported that some older bladder cancer patients cited their age as a determining factor when considering type of UD [27]. Studies suggest that many cystectomy patients are unsatisfied with the amount of information their doctors provide about diversion choices [28]. Future research should explore how the observed patterns of UD receipt are shaped by information provided to

patients, shared decision-making between patient and surgeon, and surgeon recommendations. Interviews or survey data could fill in these gaps.

In our study, the number of surgeries performed per tenure year, per surgeon was relatively low (0.2 to 14.3). These results indicate that many urologists who perform cystectomies in community settings are not sub-specialists or high-volume cystectomy surgeons, consistent with a recent analysis of 6-month case log data of urologists certified between 2003 and 2013 from the American Board of Urology [29]. In that study, 50% of cystectomies were performed by a urologist who logged only one case during the certification period. Median number of cystectomies performed was 2 (interquartile range 1–3) with the top 10% of urologists performing 5 or more cystectomies. Oncology specialty and non-private practice type were both independently associated with the top 10% of cystectomy volume. These rates remain important to consider in future research, given that 40% of cystectomies are performed in community settings [30].

Compared with academic centers, the patient population in our study sites is quite large (approximately 8.5 million members), as are the number of practice groups, hospitals, and treating urologists. Geographic location, clinic schedule, and surgeon sub-specialization can influence which surgeon treats a particular bladder cancer patient. Patients usually do not request their surgeon. However, within a large group practice with easy referrals, if their primary urologist is not a neobladder expert, they can receive a neobladder from a surgeon with this training. This may help to explain why the surgeon factors we measured did not predict which UD patients received.

Strengths of this study include being the largest multi-site study in the U.S. to date examining predictors of UD type in community settings defined by integrated care, and being one of the first studies to systematically evaluate both patient and surgeon factors. Our results are also generalizable to community practices as it involves institutions with substantial variability in practice patterns. For example, in KPSC, there are more sub-specialists available to perform neobladders compared with KPNC and KPNW. In KPNW, it is common for a second surgeon to assist in cystectomies, so that expertise is higher than case volume numbers suggest. In KPNC, these surgeries were usually performed by general urologists; however, patients began to be directed to surgeons with surgical oncology training near the end of the study period in 2015.

Limitations include no direct access to information on patient and physician preferences, or decision-making processes. We also acknowledge that selection bias may influence if a patient undergoes cystectomy (compared to chemoradiation therapy) or where they receive it, however our primary objective was to examine factors associated with the use and receipt of UD type in a surgically treated cohort.

Conclusions

Receipt of IC versus continent UD is largely determined by patient factors. While surgeons also play a significant role in decision-making, the specific factors driving this process are not easily characterized. Accordingly, a model consisting of readily available patient factors

offers a valid approach for minimizing treatment assignment bias in observational comparative effectiveness research on outcomes associated with urinary diversion type. Future studies should explore more nuanced surgeon-related factors, such as beliefs about UD options and likely outcomes, and communication and decision-making approaches with patients.

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Table 1.

Characteristics of patients in the Bladder Cancer Quality of Life (BCQOL) Study (n=991)

Patient Characteristics	Received Ileal Conduit (n=794)		Received Neobladder/Pouch (n=197) ^a		Total (n=991)		p-value ^b
	n	%	n	%	n	%	
Age at cystectomy							<.001
Mean (SD)	71.8 (9.1)		62.2 (9.3)		69.9 (9.9)		
Sex							.002
Male	602	75.8	166	84.3	768	77.5	
Female	192	24.2	31	15.7	223	22.5	
Race							.38
White	672	84.6	166	84.3	838	84.6	
Non-White	122	15.4	31	15.7	153	15.4	
Hispanic							.86
No	725	91.3	180	91.4	905	91.3	
Yes	69	8.7	17	8.6	86	8.7	
GFR (kidney function) within 12 weeks prior to Cystectomy (mL/min/1.73 m²)							<.001
>90 (normal)	89	11.2	27	13.6	116	11.7	
61–90 (mildly reduced)	385	48.5	127	64.7	512	51.7	
45–60 (moderately reduced)	192	24.2	36	18.2	228	23	
<45 (moderately to severely reduced)	128	16.1	7	3.5	135	13.6	
Mean (SD)	66.3 (22.5)		74.1 (16.9)		67.8 (21.7)		
Liver impairment (cirrhosis diagnosis and/or abnormal LFT)							.35
No	705	88.8	180	91.4	885	89.3	
Yes	89	11.2	17	3.6	106	10.7	
Charlson-Deyo Comorbidity Index with malignancy index (12 months prior to cystectomy)^c							<.001
2	210	26.5	98	49.8	308	31.1	
3	153	19.3	38	19.3	191	19.3	
4+	431	54.3	61	31.0	492	49.7	
mean (SD)	4.3 (2.3)		3.3 (1.9)		4.1 (2.2)		
min-max	2 – 12		2 – 11		2 – 12		
AJCC stage at first bladder cancer diagnosis							.001
0a	84	10.6	21	10.6	105	10.6	
0is	25	3.2	8	4.0	33	3.3	
I	144	18.2	44	22.2	188	19	
II	204	25.7	72	36.4	276	27.8	
III	151	19.0	23	11.7	174	17.6	
IV	186	23.4	29	14.7	215	21.7	
Time between first bladder cancer diagnosis to surgery (months)							.98

Patient Characteristics	Received Ileal Conduit (n=794)		Received Neobladder/Pouch (n=197) ^a		Total (n=991)		p-value ^b
	n	%	n	%	n	%	
mean (SD)	15.2 (36.1)		14.7 (26.6)		15.1 (34.4)		
min-max	0.3 – 370.9		0.7 – 176.6		0.3 – 370.9		
1st quartile-3 rd quartile	1.7 – 9.4		2.6 – 11.1		1.8 – 9.6		
History of pelvic cancer before bladder cancer diagnosis							.053
No	709	89.3	187	95.0	896	90.4	
Yes	85	10.7	10	5.0	95	9.6	
Neoadjuvant therapy							.066
No	770	97.0	187	94.9	957	96.6	
Yes	24	3.0	10	5.1	34	3.4	
BMI within 3 months before surgery (kg/m²)							.52
24.9 (normal weight)	242	30.5	55	27.9	297	30.0	
25.0–29.9 (overweight)	336	42.3	85	43.2	421	42.5	
30.0–34.9 (obese)	151	19.0	42	21.3	193	19.5	
35.0 (obese class II,III)	65	8.2	15	7.6	80	8.1	
Mean (SD)	27.6 (5.0)		28.2 (5.2)		27.7 (5.0)		

^a 173 neobladders and 24 continent pouches

^b p-value accounting for nesting of patients within surgeons (random effect) nested within sites (fixed effect)

^c Baseline comorbidity score = 2 since all patients had at least a bladder cancer diagnosis

Table 2.

Characteristics of surgeons who performed urinary diversion (UD) surgeries on patients in the BCQOL Study (N=169)

Surgeon Characteristics	Surgeons who performed only Ileal Conduit surgeries (n=99)		Surgeons who performed Neobladder, Pouch, and/or Ileal Conduit surgeries (n=70)		p-value ^b
	n	%	n	%	
Surgeon volume^a					
min-max		0.2 – 4.7		0.2 – 14.3	
Mean (SD)		0.8 (0.70)		2.1 (2.95)	.016
Years since medical school graduation					.56
10 years	35	35.4	26	37.1	
10 - 15 years	17	17.2	18	25.7	
15 - 24 years	17	17.2	12	17.1	
> 24 years	30	30.3	14	20.0	
Mean (SD)		17.0 (13.7)		15.3 (13.4)	
Years employed at Kaiser Permanente					.60
< 5 years	25	25.3	14	20.0	
5 years	74	74.8	56	80.0	
Mean (SD)		4.8 (1.24)		5.0 (1.05)	
Clinical fellowship					.24
No	78	78.8	42	60.0	
Yes	21	21.2	28	40.0	

^a Calculated as total number of UD surgeries/tenure years employed at Kaiser Permanente across all study calendar years

^b p-value accounting for nesting of patients within surgeons (random effect) nested within sites (fixed effect)

Table 3.

Patient factors associated with odds of receiving an ileal conduit vs. neobladder/continent pouch in bladder cancer patients with cystectomies performed in community settings between 2010–2015, BCQOL Study (n=991)

Patient Characteristics		Odds Ratio ^a	95% Confidence interval ^a		Relative Importance ^b
Age (10-year increments)		4.31 *	3.14	5.91	0.93
Sex					0.18
	Male	Ref			
	Female	2.39 *	1.32	4.35	
Race					0.12
	White	Ref			
	Non-White	1.35	0.71	2.59	
Hispanic					0.12
	No	Ref			
	Yes	1.34	0.62	2.91	
Kidney Function (mL/min/1.73 m ²)					0.40
	>90 (normal)	Ref			
	61–89 (mildly reduced)	0.85	0.41	1.74	
	45–60 (moderately reduced)	0.86	0.37	2.00	
	<45 (moderately to severely reduced)	4.30*	1.38	13.36	
Liver impairment (cirrhosis diagnosis or abnormal LFT)					0.12
	No	Ref			
	Yes	1.29	0.60	2.78	
Charlson-Deyo Comorbidity Score					0.46
	2	Ref			
	3	1.26	0.68	2.33	
	4+	2.32 *	1.34	4.01	
AJCC Stage at First Diagnosis					0.27
	0a	0.79	0.34	1.85	
	0is	0.73	0.24	2.19	
	I	0.98	0.52	1.84	
	II	Ref			
	III	2.21 *	1.05	4.65	
	IV	4.00 *	1.97	8.09	
History of Pelvic Cancer Before Bladder Cancer Diagnosis					0.14
	No	Ref			
	Yes	1.54	0.62	3.82	
Time Between First Bladder Cancer Diagnosis to Surgery (months)		1.00	0.99	1.01	0.11
Neoadjuvant Therapy					0.14
	No	Ref			

Patient Characteristics	Odds Ratio ^a	95% Confidence interval ^a	Relative Importance ^b
Yes	0.53	0.14	2.00
BMI per 5 unit increase within 3 months before surgery (kg/m²)	1.04	0.84	1.29
			0.14

* Statistically significant (p<0.05)

^aFrom multivariable mixed effects logistic regression model with surgeon as a random effect, and region as a fixed effect. All variables listed were included in the model.

^bUsing the adequacy index, defined as the fraction of the full model $-2 \log$ likelihood that could be accounted for with a model including just that variable itself.