Quality Improvement in Cystectomy Care with Enhanced Recovery (QUICCER) study

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Objectives

To determine if patients managed with a cystectomy enhanced recovery pathway (CERP) have improved quality of care after radical cystectomy (RC), as defined by a decrease in length of hospital stay (LOS) without an increase in complications or readmissions compared with those not managed with CERP.

Subjects and Methods

The Quality Improvement in Cystectomy Care with Enhanced Recovery (QUICCER) study was a non-randomized quasi-experimental study. Data were collected between June 2011 and April 2015. The CERP was implemented in July 2013. The primary endpoint was LOS. Secondary endpoints were quality scores, complications and readmissions. Multivariable regression was performed. Propensity score matching was carried out to further simulate randomized clinical trial conditions. A CERP quality composite score was created and evaluated with regard to adherence to CERP elements.

Results

The study included 79 patients managed with CERP and 121 who were not managed with CERP. After matching, there were 75 patients in the non-CERP group. The LOS was significantly different between the groups: the median LOS was 5 and 8 days for the CERP and non-CERP group, respectively (P < 0.001). Multivariable linear regression showed that any complication was the most significant predictor of total LOS at 90 days after RC. The higher the quality composite score the shorter the LOS (P < 0.001). There was no association between CERP and a greater number of complications or readmissions.

Conclusions

Audited quality measures in the CERP are associated with a reduction in LOS with no increase in readmissions or complications. The CERP is important for the future improvement of peri-operative care for RC and provides an opportunity to improve the quality of care provided.

Keywords
cystectomy, enhanced recovery after surgery, quality improvement, fast track, outcomes, #BladderCancer, #blcsm

Introduction

Every year, ~10 000 radical cystectomy (RC) operations are performed across the USA [1]. Length of hospital stay (LOS) is one of the most reported quality indicators for patients undergoing RC [2–7] and RC continues to be associated with a prolonged LOS of 8–11 days [8]. In addition, RC is associated with significant morbidity. Worldwide, postoperative complications of RC are estimated to occur in 30–80% of patients and readmissions are necessary in up to 30% of patients after surgery [2,3,9,10]. Given the prolonged LOS, and the complication and readmission rates, there is much room for improvement in current RC care.

Over the past 20 years, there have been many efforts to reduce complications and LOS after RC [11–13]. The use of various enhanced recovery after surgery (ERAS) programmes, which are a collection of multidisciplinary and multimodal evidence-based interventions, can improve postoperative LOS in patients who have undergone complex surgery [2–7]. ERAS pathways provide a framework for planning, setting patient expectations and devising interventions to prepare and reduce the physiological and the psychological stress of a major operation. Previous literature has associated ERAS pathways with decreased variations in care and improved quality of care, which often results in decreased costs [6,13]. Many variations exist in current ERAS protocols as a result of surgeon-specific, cultural, hospital and regional differences [2–7,14–16], and, most importantly, ERAS pathways are still not considered the standard of care for patients undergoing RC [16].
Using a framework for the evaluation of the surgical care delivered is important for improving the quality of the care rendered, and as a measurement of surgical care quality [13,17,18]. LOS, among other objective care quality measurements, is used as part of the framework for evaluating quality outcomes of RC [11,12]. Evaluation of the process and outcome portion of the framework, with standard reporting methods with compliance auditing, allows the quality improvement outcomes to be reproduced [11,12,18].

The aim of the present study, the Quality Improvement in Cystectomy Care with Enhanced Recovery (QUICCER) study, was to determine if patients managed with a cystectomy enhanced recovery pathway (CERP) have improved quality of care after RC, as defined by a decrease in LOS without an increase in complications or readmissions compared with those not managed with CERP.

Materials and Methods

Patient Selection

The QUICCER study was a non-randomized clinical study conducted using a quasi-experimental design, with a comparison and a treatment group. In July 2013, after institutional review board approval, a CERP was implemented using evidence-based ERAS interventions, with the purpose of augmenting recovery in patients undergoing RC. CERP interventions are listed in Figs 1 and 2. The CERP for this study varied from the previously published RC ERAS pathway by not using home i.v. fluids but administering a gentle bowel regimen.

From June 2011 to April 2015, 200 consecutive patients with bladder cancer were included. All patients underwent RC with bowel resection for urinary diversion and pelvic lymph node dissection. No patients were excluded from this study. The analysis consisted of data collected from 121 retrospective patients not managed with the CERP (non-CERP group) and 79 prospective patients managed with the CERP. All the patients in the CERP group provided written informed consent. The retrospective patient group was identified using departmental records. After CERP implementation, patients on the CERP received all interventions for which they were eligible, based on medical comorbidities and surgical factors. The interventions received by each patient were tracked. Regardless of the interventions received, number of days spent in the intensive care unit, ventilator requirements and additional surgical procedures performed at the same time as RC, all patients were included in the final analysis. Patients were included in an intention-to-treat analysis and no patients were excluded from these analyses.
Fig. 2 Details of the cystectomy enhanced recovery pathway (CERP). BG, blood glucose; BD, twice daily; BM, bowel movement; Cipro, ciprofloxacin; CLD, clear liquid diet; d/c, discharge; DVT, deep vein thrombosis; DM2, diabetes mellitus type II; H; hours; ICU, intensive care unit; IV, intravenous; LMWH, low molecular weight heparin; NaHCO3, sodium bicarbonate; NPO, nothing by mouth; NG, nasogastric; N/V, nausea/vomiting; OG, orogastric; O2, oxygen; OR, operating room; OT, occupational therapy; PCP, primary care doctor; PE, pulmonary embolism; PO, by mouth; POD, postoperative day; prn, as needed; PT, physical therapy; Qh, every 6 hours; Rx, prescription; SCDs, sequential compression devices; SW, social work; WOCN, wound ostomy continence nurse; w/in, within. *Prednisolone, albuterol, CLD, weight loss screen, BMI, if any risk factors for malnutrition, start protein drinks TID; †Four night before, two morning of, given in clinic. Exclusion: any issues with airway protection; ‡If platelets to track to 1.5 L P, c/t IVF early; ‡pts may have nutrition drinks they prefer, ensure etc; §Exclusion: chronic opioid dependence; ¶For HR–60, excessive secretions, neuromuscular disorders; ‖Antibiotic redosing for $1 L estimated blood loss or time in OR; ‖‖HCO3 if <18 at d/c; ‖‖‖all pts to get Ciprofloxacin 1 h before follow-up appointment for stent removal, renal dose adjust if needed usually at 7–10 days postop; ‖‖‖‖NSAIDs if history of bleeding ulcer disease. Hold for renal dysfunction, celecoxib okay for mild renal dysfunction, continue to monitor daily BMP. On celecoxib or ketorolac, should be on PPI; ≥30 min walking twice daily or return to ptp previous exercise routine if more vigorous; ‡Superior GI tolerance to opioids, try to avoid strong opioids, hold for previous history of seizures, also if pto SSRIs and anything that could cause serotonin syndrome; †patients should have Heparin 5000 SC re-dosed at 8 h intervals while in the OR; ††renal and weight adjusted as necessary.

### Data Collection

Using Research Electronic Data Capture (REDCap) tools, a database was created and maintained in accordance with the scope of the project [19]. Data collected included demographics, operative characteristics, complications, readmissions and LOS (days). To confirm accurate and valid patient data abstraction, a kappa value was calculated. National Surgical Quality Improvement Project (NSQIP) database points were compared with the data abstracted for this project [20]. A total of 20 data points were compared to calculate the kappa value for data validity. NSQIP data were compared with abstracted data points for 30 days after RC from both sources to provide the most precise kappa value.

### Treatment and Follow-up

All patients were treated by one of four surgeons. There was no change in open surgical technique during the study period. Robotic surgery was introduced by three of our surgeons in 2007; thereafter, all patients seen by these three surgeons had robot-assisted RC performed without discrimination. Consistently, 80% of the urinary diversions were performed intracorporeally. Additionally, there was no difference in the surgical techniques during this time period. Before the implementation of the CERP, there was no standard pathway for peri-operative RC care at our institution and the discharge criteria included: tolerating a regular diet; passage of flatus; clearance by physical therapist; pain controlled with oral medications; and achievement of ostomy competence as determined by a certified wound ostomy nurse. After CERP implementation, all discharge criteria were the same except that the patient had to be able to tolerate ≥1 L of regular diet. There were no CERP modifications during the study period. Patients were discharged without any home interventions other than a home healthcare/visiting nurse service for ostomy support (no home i.v. fluids or medication administration).
Follow-up for the CERP group was obtained from telephone calls by a trained nurse practitioner on post-discharge days 2, 7–10 and 30, with standardized predefined questions to screen for any complications or readmissions. Follow-up was also obtained at the 90-day post-surgery office visits with the surgeon. For the non-CERP group each chart was retrospectively reviewed.

Endpoints

The primary outcome was LOS, which was recorded as the number of midnights the patient spent in hospital. Secondary endpoints were considered complications and readmissions. The NSQIP definitions of complications were used for available variables; full descriptions are in Appendix S1 [20]. NSQIP definitions were applied to the entire 90-day follow-up period. Other complication categories were defined with available objective information (i.e. ileus was defined by an attending radiologist read as ‘ileus’ on radiographs, placement of a nasogastric tube, and/or the need for total parenteral nutrition (TPN) because of enteral feeding intolerance).

Readmissions were considered separately from complications. All patients included had 90 days of follow-up. Standard Clavien grades were reported for complications (I, II, IIIa, IIIb, Iva, IVb, V) [21]. Recommended quality indicators for bladder cancer care were used to allow quality indicator assessment using Dobedian’s framework: structure; process; and outcome [11–13,17,18]. Total hospital days were calculated for 30 and 90 days after RC, this included the total number of hospital days including the initial LOS and all readmission days.

Statistical Analyses

The sample size needed to show a 2-day decrease in LOS was calculated a priori, which required 51 patients in each arm with $\alpha < 0.05$ and $\beta < 0.80$. All $P$ values were two-sided and considered to be significant at $<0.05$.

Continuous and ordinal covariate distributions were summarized with medians, interquartile range (IQR) using the first (Q1) and third quartiles (Q3). Univariable analyses was performed using the Kruskal–Wallis test [22]. Categorical covariates were summarized with counts and percentages and then compared between the two groups using a chi-squared and Fisher’s exact test, as appropriate [22]. A test for trend was performed in the univariable and multivariable analyses [22]. Linear regression multivariable analyses were used for

| Variables Used to Create the Propensity Matching Score |
|------------------------------------------------------|
| Age at surgery                                      |
| Sex                                                  |
| AHRQ socioeconomic index                             |
| Body mass index                                      |
| Total pack years for tobacco smoking                 |
| Age adjusted Charlson comorbidity index score        |
| Neoadjuvant chemotherapy                             |

A

B

C

Fig. 3 Propensity Score Matching. (A) Variables used to create the Propensity Matching Score. (B) Distribution of propensity scores prior to matching. (C) Distribution of propensity scores after matching. AHRQ, Agency for Healthcare Research and Quality; ASA, American Society of Anesthesiologists.
continuous variables. Logistic regression was used for dichotomous variables. A comprehensive index, developed by the Agency for Healthcare Research and Quality (AHRQ), was used to evaluate any socio-economic differences between the two groups [23]. The AHRQ index is determined for each zip code and includes: percentage of persons below the federal poverty line; median household income; median value of owner-occupied homes; low education status (percentage of persons aged ≥25 years with a lower than 12th grade level of education), high education status (percentage of persons aged ≥25 years with at least 4 years of college education); percentage of households containing one or more person per room; and percentage of persons aged >16 years who are in the labour force and actively seeking work, but are unemployed.

The two-arm quasi-experimental method reduces selection bias based on patient characteristics, but it is not fully equivalent to randomization because certain patient characteristics may change in a systematic manner over time (e.g. an increase in female patients in the referral pattern). To account for the non-randomized nature of the present study, propensity score matching was used to match patients on the probability that they would be in the CERP group [24]. The patients in the non-CERP group were matched 1:1 using the nearest-neighbour method with CERP patients, where the absolute difference between propensity scores was ≤0.01 [24]. Items incorporated into the propensity score model are shown in Fig. 3A. The propensity score and resultant matched score results with the recommended diagnostic tests are shown in Fig. 3B,C, respectively [25].

Additionally, for the CERP process quality indicator evaluation, a composite score was created for adherence to the CERP and was calculated for both the CERP and non-CERP groups [13,17,18]. The CERP quality composite score included pathway elements that could be tracked objectively. The components of the quality score are listed in Fig. 4A.

Multivariable analysis for the primary endpoint included a generalized linear regression model and a logistic regression model. Linear regression was used to better capture associations with the postoperative day (POD) on which the patient was discharged and complications over the 90-day follow-up. The logistic regression model used the primary outcome converted to a binary variable (≤5 vs >5 days). An LOS of 5 days was chosen because the CERP was designed for discharge on POD 3–5. Logistic regression was used to determine variable associations with discharge in ≤5 vs >5 days. Multivariable analysis was performed for the secondary endpoints using logistic regression. All variables with a P value of <0.10 in univariable analysis were included in the respective multivariable analysis. Model-based 95% CIs for a difference in medians were used to report the univariable and multivariable comparisons [22,26]. Clavien grading was analysed separately to avoid overfitting of the model. Linear regression modelling was also carried out for total hospital days 30 and 90 days after RC. An age-adjusted Charlson comorbidity index was used because it provides a more comprehensive assessment of comorbidities and is validated in patients undergoing RC [27].

All statistical analyses were performed using SAS 9.3 software.

**Results**

**Baseline Characteristics**

Distributions of the baseline demographics and operative characteristics for both groups before and after propensity

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**Fig. 4 (A)** Components of the composite score for postoperative cystectomy enhanced recovery pathway (CERP) adherence. (B) Relationship between the composite score and length of stay. NG, nasogastric tube; h, hours; NSAIDs, nonsteroidal anti-inflammatories.
Table 1 Baseline characteristics and demographics before and after propensity score matching.

| Variable                                      | CERP N = 79 | Non-CERP N = 121 | P value | Matched Non-CERP N = 75 | Matched P value |
|-----------------------------------------------|-------------|------------------|---------|-------------------------|-----------------|
| Sex: male, n (%)                              | 49 (62.0)   | 99 (81.8)        | 0.002   | 54 (72.0)               | 0.189           |
| Median (Q1–Q3) age at surgery, years          | 70.6 (65.2–77.7) | 69.5 (61.9–77.0) | 0.335   | 73.9 (64.1–79.2)        | 0.321           |
| ASA score, n (%)                              | 3.0 (3.0)   | 3.0 (3.0)        | 0.303   | 3.0 (3.0)               | 0.915           |
| Median (Q1–Q3) BMI, kg/m²                      | 27.8 (24.7–31.2) | 29.1 (24.7–32.6) | 0.389   | 27.9 (24.1–31.9)        | 0.927           |
| Neoadjuvant chemotherapy, n (%)                | 22 (27.9)   | 24 (19.8)        | 0.188   | 15 (20.0)               | 0.265           |
| Previous pelvic radiation, n (%)              | 13 (17.7)   | 11 (9.1)         | 0.071   | 11 (14.7)               | 0.667           |
| Smoker, n (%)                                  | 14 (17.7)   | 27 (22.3)        | 0.432   | 13 (17.3)               | 0.950           |
| Median (Q1–Q3) pack-years‡                    | 20 (0.0–35.0) | 22.5 (0.0–40.0)  | 0.223   | 20 (0.0–40.0)           | 0.337           |
| Median (Q1–Q3) age-adjusted Charlson comorbidity index | 5 (4–6) | 4 (3–6) | 0.490 | 5 (4–6) | 0.769 |
| Race: white, n (%)                            | 75 (94.9)   | 119 (98.4)       | 0.165   | 73 (97.3)               | 0.570           |
| Median (Q1–Q3) AHRQ socio-economic index score¶ | 57.4 (54.4–59.5) | 56.8 (54.2–59.6) | 0.964   | 56.6 (54.1–60.3)        | 0.648           |
| Marital status: married, n (%)                 | 52 (65.8)   | 87 (71.9)        | 0.734   | 51 (68.0)               | 0.962           |
| Discharge destination                          | 0.792       | 0.792            |         |                         |                 |
| Home care or self-care, n (%)                 | 10 (12.7)   | 13 (10.8)        | 0.100   | 10 (13.5)               | 0.246           |
| Home health service, n (%)§                   | 58 (74.4)   | 93 (77.5)        | 0.551   | 55 (74.3)               |                 |
| Skilled nursing facility, n (%)               | 8 (10.3)    | 10 (8.3)         | 0.459   | 10 (13.5)               | 0.586           |
| Urinary diversion, n (%)                      |             |                  |         |                         |                 |
| Ileal conduit                                 | 71 (99.9)   | 113 (93.4)       | 0.714   | 71 (94.7)               |                 |
| Indiana pouch                                 | 3 (3.8)     | 1 (0.8)          | 0.044   | 1 (1.3)                 |                 |
| Neobladder                                    | 5 (6.3)     | 7 (5.8)          | 0.766   | 3 (4.0)                 | 0.090           |
| Additional procedure, n (%)‡                  | 0 (0)       | 0 (0)            | 0.545   | 0 (0)                   | 0.901           |
| Median (Q1–Q3) lymph node yield               | 18 (10.5–21.5) | 31 (15–24)       | 0.086   | 18 (12–25)              | 0.155           |
| Physician, n (%)                              |             |                  |         |                         |                 |
| 1                                             | 8 (10.1)    | 2 (1.7)          | 1.000   | 1 (1.3)                 |                 |
| 2                                             | 14 (17.7)   | 21 (17.4)        | 0.554   | 13 (17.3)               |                 |
| 3                                             | 22 (27.9)   | 41 (33.9)        | 0.485   | 25 (27.9)               |                 |
| 4                                             | 35 (44.3)   | 57 (47.1)        | 0.687   | 36 (48.0)               |                 |
| Median (Q1–Q3) EBL, L                        | 0.5 (0.3–1.2) | 0.7 (0.3–1.3)   | 0.485   | 0.6 (0.3–1.2)           | 0.817           |
| Surgical technique: robot-assisted laparoscopic, n (%) | 44 (55.7) | 64 (52.9) | 0.697 | 39 (52.0) | 0.646 |
| Median (Q1–Q3) operating time, h             | 7.2 (6.4–8.5) | 6.8 (5.9–8.2)   | 0.095   | 6.8 (5.7–8.1)           | 0.059           |
| Median (Q1–Q3) total units of PRBCs administered | 0 (0–3) | 0 (0–3) | 0.551 | 0 (0–2) | 0.222 |
| Pathological characteristics, n (%)          |             |                  |         |                         |                 |
| Stage ≥T3a                                    | 26 (32.9)   | 43 (35.5)        | 0.703   | 22 (29.3)               | 0.632           |
| Node-positive                                 | 12 (15.2)   | 26 (21.5)        | 0.515   | 13 (17.3)               | 0.718           |

AHRQ, Agency for Healthcare Research and Quality; ASA American Society of Anesthesiologists; BMI, body mass index; CERP, cystectomy enhanced recovery pathway; EBL, estimated blood loss; NOx, not otherwise specified; PRBCs, packed red blood cells; RC, radical cystectomy; Q1, first quartile; Q3, third quartile. Demographics and baseline characteristics of the patients both before and after propensity score matching. There was no difference between the two groups with regard to other demographics including the variables: age at diagnosis, chronic obstructive pulmonary disease, diabetes mellitus, Charlson comorbidity index, ethnicity, insurance primary and secondary payers, distance from home to the hospital, and the distribution of RC among the four physicians, these variables are not listed in the above table. *Current smoker. †Total pack years if ever or current smoker. ‡AHRQ socio-economic index score incorporates for each patient’s zip code the percentage of persons aged ≥16 years in the labour force who are unemployed and actively seeking work, percentage of persons below the federally defined poverty line, median household income (standardized to have values 0 to 100), median value of owner-occupied homes (standardized to values 0–100), percentage of persons aged ≥25 years with at least 4 years of college education and the percentage of households containing one or more person per room. ¶Patients were discharged without any home interventions other than a home healthcare/visiting nurse service for ostomy support (no home i.v. fluids or medication administration). §Additional procedure at the same time as RC, i.e. nephroureterectomy.

scoring are shown in Table 1. After propensity matching, significant differences existed in the operating time for the RC procedure.

Complications according to Clavien grade and individual complications are shown in Table 2. Complications more common in the non-CERP group included postoperative myocardial infarction, ileus, requirement for TPN, and ventilator support for ≥48 h. There was no difference in the incidence of overall complications between the non-CERP and CERP groups. Table 2 includes all emergency department visits and readmissions. There were no differences between the two groups in the number of readmissions and emergency department visits.

Additionally, the time to readmission or emergency department visit was not significantly different between the two groups.

Data collection was validated using the NSQIP abstractor with a kappa value of 0.76, which was considered good congruence.
Table 2 Complications and readmissions.

|                      | CERP N = 79 | Non-CERP N = 121 | P value | Matched CERP N = 75 | Matched P value |
|----------------------|-------------|-------------------|---------|---------------------|-----------------|
| Any complication, n (%) | 56 (70.9)   | 99 (81.8)         | 0.070   | 64 (85.3)           | 0.034           |
| Clavien grade complications, n (%) |             |                   | 0.722   |                     | 0.358           |
| Grade I               | 0 (0.0)     | 6 (6.1)           |         | 4 (6.3)             |                 |
| Grade II              | 27 (48.2)   | 57 (57.6)         |         | 35 (54.7)           |                 |
| Grade IIIa            | 18 (32.1)   | 15 (15.2)         |         | 10 (15.6)           |                 |
| Grade IIb             | 6 (10.7)    | 7 (7.1)           |         | 4 (6.3)             |                 |
| Grade IVa             | 1 (1.8)     | 6 (6.1)           |         | 4 (6.3)             |                 |
| Grade IVb             | 1 (1.8)     | 2 (2.0)           |         | 2 (3.1)             |                 |
| Grade V               | 3 (5.4)     | 6 (6.1)           |         | 5 (7.8)             |                 |
| Individual complications*, n (%) |             |                   |         |                     |                 |
| Postoperative MI      | 0 (0)       | 10 (8.3)          | 0.007   | 7 (9.3)             | 0.006           |
| Sepsis                | 25 (31.7)   | 51 (42.2)         | 0.135   | 31 (41.3)           | 0.212           |
| UTI                   | 26 (32.9)   | 58 (47.9)         | 0.035   | 34 (45.3)           | 0.138           |
| Clostridium difficile | 7 (8.9)     | 9 (7.4)           | 0.792   | 4 (5.3)             | 0.535           |
| Deep SSI              | 2 (2.5)     | 6 (5)             | 0.483   | 2 (2.7)             | 1.000           |
| Organ space infection | 9 (11.4)    | 15 (12.4)         | 0.831   | 11 (14.7)           | 0.546           |
| Superficial SSI       | 5 (6.3)     | 15 (12.4)         | 0.162   | 10 (13.3)           | 0.178           |
| Pneumonia             | 2 (2.5)     | 9 (7.4)           | 0.206   | 5 (6.7)             | 0.267           |
| ileus                 | 24 (30.4)   | 65 (53.7)         | 0.001   | 42 (56)             | 0.001           |
| Gastrointestinal bleed| 6 (7.6)     | 3 (2.5)           | 0.159   | 3 (4)               | 0.496           |
| Bowel anastomotic leak| 1 (1.3)     | 3 (2.5)           | 1.000   | 3 (4)               | 0.357           |
| NG insertion†         | 15 (19.5)   | 27 (22.3)         | 0.635   | 18 (24)             | 0.499           |
| Urine leak            | 6 (7.6)     | 6 (5)             | 0.443   | 4 (5.3)             | 0.746           |
| Delirium              | 3 (3.8)     | 8 (6.6)           | 0.532   | 5 (6.7)             | 0.487           |
| AKI                   | 6 (7.6)     | 4 (3.3)           | 0.197   | 3 (4)               | 0.496           |
| Transfusion           | 40 (50.6)   | 52 (43)           | 0.476   | 34 (45.3)           | 0.523           |
| DVT                   | 6 (7.6)     | 12 (9.9)          | 0.624   | 9 (12)              | 0.422           |
| PE                    | 2 (2.5)     | 7 (5.8)           | 0.166   | 3 (4)               | 0.675           |
| Ventilator >48 h      | 4 (5.1)     | 11 (9.1)          | 0.290   | 10 (13.3)           | 0.095           |
| Night of surgery ventila† | 12 (15.2) | 20 (16.5)        | 0.801   | 13 (17.3)           | 0.718           |
| Interventional radiology procedure§ | 23 (29.1) | 25 (20.7)             | 0.171   | 19 (25.3)           | 0.599           |
| Return to operating room| 5 (6.3) | 11 (9.1)         | 0.482   | 8 (10.7)            | 0.393           |
| TPN                   | 6 (7.6)     | 38 (31.4)         | <0.001  | 27 (36)             | <0.001          |
| Days of TPN, Med (Q1–Q3) | 4.0 (2.0–6.0) | 7.0 (4.8–8.5) | 0.121 | 7.0 (5.3–8.5) | 0.078 |
| Mortality, n (%)      |             |                   |         |                     |                 |
| 30-day all-cause mortality | 3 (3.8) | 3 (2.5)           | 0.682   | 2 (2.7)             | 1.000           |
| 90-day all-cause mortality | 5 (6.3) | 10 (8.3)         | 0.785   | 4 (5.3)             | 0.322           |
| 90-day bladder cancer specific survival | 71 (97.3) | 108 (96.4) | 1.000 | 71 (97.2) | 1.000 |
| Readmissions, n (%)   |             |                   |         |                     |                 |
| ED visit              | 33 (41.8)   | 44 (36.4)         | 0.412   | 26 (38.2)           | 0.501           |
| Any readmission       | 31 (39.4)   | 44 (36.4)         | 0.681   | 25 (33.3)           | 0.446           |
| Readmission within 30 days | 24 (30.8) | 34 (28.3)         | 0.713   | 20 (27)             | 0.721           |
| Median (Q1–Q3) hospital days for readmission | 5 (4–9) | 4 (2–8)           | 0.297   | 4.5 (3.10) | 1.000 |
| Median (Q1–Q3) POD to ED visit, days | 15 (8–43) | 19 (13–54)       | 0.158   | 21 (13–51)          | 0.181           |
| Median (Q1–Q3) POD to ED visit, days | 12 (4–36) | 12 (5–35)        | 0.812   | 14 (3–31)           | 0.953           |
| Median (Q1–Q3) POD to readmission, 6.5 (4–14) | 8 (3–18) | 0.724 | 10 (3–18.5) | 0.670 |

AKI, acute kidney injury; CERP, cystectomy enhanced recovery pathway; CVA, cerebrovascular accident; DVT, deep vein thrombosis; ED, emergency department; MI, myocardial infarction, NG, nasogastric tube; PDD, post discharge day from initial hospital stay after RC. PE, pulmonary embolism; POD, postoperative day; Q1, first quartile; Q3, third quartile; SSI, surgical site infection; TPN, total parenteral nutrition. Complications, mortality and readmissions. Any readmission within 90 days. All complications listed happened within the 90 days after surgery. *More than one complication possible per patient. †NG reinsertion for those who left the operating room with NG tubes. ‡From the night of POD 0 to POD 1. §All event included, emergency and otherwise.

Outcomes

The LOS was significantly different between the 79 patients in the CERP group and those in the non-CERP group, both as a continuous and categorical value. The median (IQR) LOS was 5 (4–7) days and 8 (6–14) days for the CERP and non-CERP group, respectively, as shown in Fig. 5A,B. Other significant differences between the CERP and non-CERP groups included the total LOS in the first 30 days and 90 days after RC, time to clear liquids, time to regular diet, and postoperative i.v. equivalents of morphine. Significantly more i.v. morphine equivalents were taken by the patients in the non-CERP group. There was no increase in postoperative pain scores in the CERP group. The CERP quality composite score was significant for predicting LOS. A higher quality composite score for CERP component adherence was
associated with a shorter initial LOS (Fig. 4B). The CERP outcomes are summarized in Table 3.

Multivariable Analysis

A generalized linear regression model was significant when fit with the CERP group, operating time and any complication as predictors of LOS. The model was then further fit with predictors of increased LOS. The logistic regression model for LOS ≤5 days was also significant, but predictors of LOS >5 days were ileus and CERP status.

Multivariable linear regression for the prediction of longer LOS was completed for the initial LOS, and total hospital days in the 30 and 90 days post-RC. This was adjusted for CERP status, any complication and individual complications. The initial LOS was most influenced by the CERP and any complication. Even after adjusting for any complication and operating time, CERP status remained the best predictor of initial LOS. Individual complications (considered as separate variables) were all significant predictors of a longer LOS. By 30 and 90 days after RC, individual complications and any complication were still significant predictors of LOS. By 90 days, the most significant predictor of total LOS was any complication. The results of the multivariable analyses are shown in Table 4.

Discussion

The CERP was associated with a decrease in LOS, but was not associated with an increase in complications or readmissions and represents a significant opportunity for quality of care improvement for RC. This is consistent with previous studies suggesting improved outcomes in patients who underwent RC who participated in a CERP or a CERP-like programme. This study adds to the increasing body of evidence supporting modern ERAS pathways for patients undergoing RC [7,14,28]. The quality indicators evaluated suggest a decreased LOS without increases in morbidity and mortality, with a non-statistically significant decrease in overall complications and a linear relationship between the CERP quality composite index (used as a CERP process assessment) and LOS [13].

Few quality indicators are reliably used for bladder cancer care [13]. The CERP allows the use of quality indicators of clinical endpoints including LOS, 30-day complications, 90-day complications, 30-day and 90-day mortality rates [11–13]. To improve the quality of RC care there must be reliable tools to measure it [11,12]. The quality composite score used in the present study could serve as a way to measure and compare RC postoperative care quality. Using the quality composite index as an indicator should decrease care variations and improve overall quality, eventually leading to decreased costs [12]. To our knowledge, this is the first ERAS study on RC for ascertainment of complications and readmissions, with evaluation of CERP quality indicators along with a 90-day follow-up and no patients lost to follow-up. This study differs from previous studies in that it studies patients in the USA undergoing RC where modern CERP elements were practised without variation during the study period [2,4,5,15,29,30].

The complication rate in the present study is at the higher end of reported complication rates for RC [3–6]. Despite a high rate of complications, the complication and readmission rates were not different between the CERP and non-CERP groups. Moreover, the LOS decreased with CERP regardless of the rate of complications. There was no difference in the distribution of Clavien grade complications in the study. The
AUA antibiotic best practice followed, n (%)               78 (98.7)                           93 (76.9)               <0.001 60 (80)  <0.001
ICU days                                            0 (0–0)                                    0 (0–1)                        0.144 0 (0–1)  0.047
Intra-operative fluids, L                         6.1 (4.6–8.3)                               6.4 (4.1–9.2)               0.850 6.1 (4.0–9.5)  0.691
NG continued postoperatively, n (%)               15 (19.0)                                    65 (53.7)               <0.001 41 (54.70)  <0.001
PCA                                               3 (3.8)                                    43 (35.5)               <0.001 22 (29.3)  <0.001

CERP, cystectomy enhanced recovery pathway; ICU, intensive care unit; LOS, length of hospital stay; NG, nasogastric tube; OR, operating room during anaesthesia; PCA, i.v. patient controlled analgesia pump; POD, postoperative day; Q1, first quartile; Q3, third quartile. Values are median (Q1–Q3), unless otherwise stated. *Based on the visual analogue scale of 0–10. A composite score was created as a quality marker, this is the calculated score based on the percentage of the measurable clinical interventions that were congruent with the CERP interventions, a higher composite score was associated (more of the CERP interventions carried out) with a shorter the LOS. †The patient received counseling in the clinic preoperatively and quit smoking tobacco products at least 2 weeks before RC.

Table 3 Cystectomy enhanced recovery pathway outcomes.

|                        | CERP N = 79 | Non-CERP N = 121 | P value | Matched Non-CERP N = 75 | Matched P value |
|------------------------|-------------|------------------|---------|-------------------------|-----------------|
| Length of Stay         |             |                  |         |                         |                 |
| LOS, days              | 5 (4–7)     | 8 (6–13)         | <0.001  | 8 (6–14)                | <0.001          |
| LOS ≤5 days, n (%)     | 42 (53.2)   | 11 (10.7)        | <0.001  | 8 (16.0)                | <0.001          |
| LOS first 30 PODs, days| 6 (4–14)    | 9 (7–15)         | <0.001  | 10 (7–15)               | <0.001          |
| LOS first 90 PODs, days| 7 (4–15)    | 11 (7–17)        | 0.002   | 11 (7–17)               | <0.001          |
| Time to diet and oral intake |           |                  |         |                         |                 |
| POD to clear liquid diet | 0 (0–1)  | 4 (3–5)          | <0.001  | 4 (3–5)                 | <0.001          |
| POD to regular diet    | 3 (2–3)     | 5 (4–7)          | <0.001  | 5 (4–7)                 | <0.001          |
| Oral intake, L         |             |                  |         |                         |                 |
| POD 1                  | 1.2 (0.7–1.6)| 0 (0.0–0.1)      | <0.001  | 0 (0.0–0.1)             | <0.001          |
| POD 2                  | 1.1 (0.6–1.5)| 0 (0.0–0.3)      | <0.001  | 0 (0.0–0.3)             | <0.001          |
| POD 3                  | 0.9 (0.4–1.3)| 0.3 (0.0–0.8)    | <0.001  | 0.4 (0.0–0.9)           | 0.001           |
| POD 4                  | 0.8 (0.4–1.2)| 0.7 (0.2–1.1)    | 0.265   | 0.8 (0.4–1.2)           | 0.215           |
| POD 5                  | 0.9 (0.5–1.3)| 0.7 (0.2–1.1)    | 0.165   | 0.6 (0.1–1.1)           | 0.064           |
| POD 6                  | 0.7 (0.5–1.2)| 0.4 (0.0–1.2)    | 0.363   | 0.3 (0.0–1.1)           | 0.165           |
| POD 7                  | 0.7 (0.0–0.8)| 0.4 (0.0–1.2)    | 0.933   | 0.7 (0.0–0.8)           | 0.826           |
| Pain control dose, μg  |             |                  |         |                         |                 |
| OR i.v. morphine equivalents | 43.3 (30.0–58.3)| 42.3 (33.0–60.0) | 0.685   | 40 (30.0–58.0)          | 0.728           |
| Total postoperative i.v. morphine equivalents | 12 (0–24.2) | 87.5 (24.7–195.1) | <0.001  | 87.5 (26.0–192.8)       | <0.001          |
| Total i.v. morphine equivalents | 59.3 (37.0–81.0)| 139.7 (71.0–290.0) | <0.001  | 133.4 (66.7–273.4)      | <0.001          |
| Total tramadol, mg      | 200 (500)   |                  |         |                         |                 |
| Total tapentadol, mg    | 0 (0–150)   |                  |         |                         |                 |
| POD 1 pain score*       | 2 (1–4)     | 3 (1.0–5.0)      | 0.151   | 3 (1–5)                 | 0.104           |
| POD 2 pain score        | 2 (1–4)     | 2 (1.0–4.0)      | 0.654   | 2 (1–4)                 | 0.586           |
| POD 3 pain score        | 2 (1–3)     | 2 (0.0–4.0)      | 0.901   | 2 (0–3)                 | 0.759           |
| POD 4 pain score        | 1 (0–3)     | 2 (0.0–3.0)      | 0.759   | 2 (0–3)                 | 0.662           |
| POD 5 pain score        | 1 (0–4)     | 2 (0.0–3.0)      | 0.294   | 2 (0–3)                 | 0.260           |
| POD 6 pain score        | 2 (0–4)     | 2 (0.0–3.0)      | 0.847   | 2 (0–3)                 | 0.990           |
| POD 7 pain score        | 3.5 (0–5)   | 2 (0.0–4.0)      | 0.312   | 3 (0–4)                 | 0.502           |
| Other CERP variables    |             |                  |         |                         |                 |
| Quality composite score1 | 12.5 (11.4–13.8)| 7.7 (5.8–8.8)    | <0.001  | 7.7 (5.8–8.8)           | <0.001          |
| Antiemtic use (number of doses) | 1 (0–3) | 1 (0–4)          | 0.600   | 1 (0–4)                 | 0.416           |
| Patient stopped smoking1, n (%) | 7 (8.9) | 3 (2.5)          | 0.037   | 5 (26.3)                | 0.288           |
| Antibiotics continued >24 h, n (%) | 7 (8.9) | 51 (42.2)        | <0.001  | 29 (36.7)               | <0.001          |
| AUA antibiotic best practice followed, n (%) | 78 (98.7) | 93 (76.9)        | <0.001  | 60 (80)                 | <0.001          |
| ICU days               | 0 (0–0)     | 0 (0–1)          | 0.144   | 0 (0–1)                 | 0.047           |
| Intra-operative fluids, L | 6.1 (4.6–8.3)| 6.4 (4.1–9.2)    | 0.850   | 6.1 (4.0–9.5)           | 0.691           |
| NG continued postoperatively, n (%) | 15 (19.0) | 65 (53.7)        | <0.001  | 41 (54.70)              | <0.001          |
| PCA                   | 3 (3.8)     | 43 (35.5)        | <0.001  | 22 (29.3)               | <0.001          |

likelihood is low that we failed to capture any significant morbidities. It may be that the non-CERP group had fewer complications and readmissions captured because follow-up was obtained by chart review rather than patient interviews, but, as there was no increase in complications or readmissions, this would not influence the findings of the present study. Additionally, low grade complications are common in this patient group and NSQIP complication definitions were applied to the full 90-day follow-up period, which may have inflated the complication rate compared with that in other studies. Overall, operating times in the present study are longer than most reported; the operating time was greater for the CERP group than the non-CERP group. It is important to note ~15% of patients underwent additional procedures during the same surgical intervention (such as a nephroureterectomy) and because of the operative logging system, the time record for separating the procedures was not available, and thus the total operating time was used in the present study. Regardless of the longer operating times, LOS was still shorter with CERP. Lastly, 90-day mortality was not significantly different between the groups and was within the expected 90-day mortality for age-specific survival rates [31]. Notably, with the introduction of alvimopan as part of the CERP, the number of cardiac complications was not increased.

There were no differences between the CERP and non-CERP group in baseline, operative and pathological demographics.
Furthermore, the adjusted analysis affirms the adequacy of the quasi-experimental study design with propensity score matching. The extensive comparison of baseline characteristics of the patients, their pathologies, and their operative courses helped to ensure that the analysis carried out most closely reflected the systemic change and quality improvement associated with the CERP implementation. Other measures used to control for possible sources of confounding were calculations of the AHRQ socio-economic index, data abstraction with NSQIP validation, and high study enrolment rates. A comprehensive index developed by the AHRQ was used to ensure there were no socio-economic differences between the two groups [23]. Any readmissions outside of our healthcare system discovered during CERP patient interviews, resulted in record obtaining, which was used for data abstraction. The patient accrual more than satisfied the need to detect a 2-day reduction in LOS. Additionally, no patients refused to participate in the study and none were excluded from the analysis. All of these measures allow the results found in the present study to extend CERP applicability and quality improvement to all patients undergoing RC.

Limitations of the present study include its non-randomized study design using a historical non-CERP group as the comparison, although all means of accounting for this deficiency were used. The results presented were from RCs being performed for bladder cancer so they cannot be directly extrapolated to RCs performed for non-oncological reasons. The majority of the urinary diversions were ileal conduits, so the results may not apply to other urinary diversions. The exact reason for the majority of ileal conduit urinary diversions is unknown; all patients are presented with the options of an ileal conduit, neobladder or continent catheterizable pouch. The patient’s choice of urinary diversion is honoured unless there are specific contraindications to a continent diversion. Although there was no known change over time in the surgical technique or patient selection, there may be study attributes which could not have been accounted for because they were not apparent at the time of data analysis. The study was performed at a single cancer referral centre, which may have exaggerated patient acuity compared with that seen in the general population with similar surgical requirements. Further complication comparisons were not possible because of the small number of complications in each category. Lastly, LOS is an imperfect evaluation of quality of care, but this is one of the most objective ways to analyse outcomes of ERAS programmes. LOS should be considered an acceptable quality indicator if not associated with increased readmissions or complications.

Future areas of quality improvement in RC care with the CERP should include investigation of costs, quality of life, patient urinary diversion decision-making and patient satisfaction. RCs continue to have high morbidity even with improved quality-of-care indicators. Reduction in complications and readmissions are two areas of opportunity for research which will have a high impact on RC care quality. Additional large multicentre studies to validate ERAS pathways and determine pertinent elements for reliable quality improvement outcomes are needed; however, given

### Table 4 Multivariate analyses.

| Model                                      | Variable                          | Estimate | 95% CI          | P     |
|--------------------------------------------|-----------------------------------|----------|-----------------|-------|
| Multivariable linear regression for LOS    |                                   |          |                 |       |
| $R^2 = 0.113$                              | CERP vs non-CERP                  | -4.740   | (7.567–1.914)  | 0.001 |
|                                            | Any complication                  | 3.665    | (0.226–7.104)  | 0.037 |
|                                            | Operating time                    | 0.587    | (-0.263–1.436) | 0.175 |
| Multivariable linear regression for LOS in 90 days | CERP vs non-CERP                  | -2.049   | (-5.699–1.601) | 0.214 |
|                                            | No complication vs any complication | -8.429   | (-14.940–1.918) | <0.001 |
|                                            | CERP* Any complication            | -1.069   | (-9.242–7.103) | 0.796 |
| Multivariable logistic regression for LOS ≤5 days adjusted for individual complications | CERP vs non-CERP                  | 7.337    | (2.941–18.307) | <0.001 |
|                                            | Ileus                             | 5.905    | (2.221–15.700) | <0.001 |
|                                            | TPN                              | 2.773    | (0.491–15.666) | 0.248 |
|                                            | Ventilator >48 h                  | 1.755    | (0.270–11.419) | 0.556 |
| Multivariable logistic regression for any readmissions | CERP vs non-CERP                  | 0.960    | (0.471–1.957)  | 0.911 |
|                                            | Ileus                             | 1.576    | (0.730–3.398)  | 0.247 |
|                                            | TPN                              | 0.390    | (0.128–1.190)  | 0.098 |
|                                            | Initial length of stay            | 0.980    | (0.928–1.036)  | 0.481 |

CERP, cystectomy enhanced recovery pathway; LOS, length of hospital stay; TPN, total parenteral nutrition. Multivariable analyses showed that the CERP was highly associated with a shorter LOS after adjusting for any complication and operating time. Ninety days after radical cystectomy (RC) any complication was more predictive of length of stay than CERP group. Logistic regression revealed an initial LOS after RC of <5 days was strongly predicted by CERP status and if the patient had an ileus postoperatively. There was no association with CERP status and readmissions.
the complexity of CERP implementation, a true randomized study may prove difficult [15].

In conclusion, RC remains a major source of surgical morbidity. Improved quality of care is possible with the CERP. Adherence to the CERP is associated with a shorter LOS. The CERP is a significant opportunity for quality improvement in RC care that is associated with a reduction in LOS without increasing complications or readmissions.

**Conflict of Interest**

None declared.

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**Abbreviations:** CERP, cystectomy enhanced recovery pathway; RC, radical cystectomy; LOS, length of hospital stay; ERAS, enhanced recovery after surgery; NSQIP, National Surgical Quality Improvement Project; TPN, total parenteral nutrition; IQR, interquartile range; Q1, first quartile; Q3, third quartile;
AHRQ, Agency for Healthcare Research and Quality; POD, postoperative day.

Supporting Information
Additional Supporting Information may be found in the online version of this article:

Appendix S1. NSQIP, National Surgical Quality Improvement Project; SSI, surgical site infection; UTI, urinary tract infection; CVA, cerebrovascular accident; OR, operating room; Temp, temperature; HR, heart rate; bpm, beats per minute; RR, respiratory rate; PaCO₂, partial pressure of carbon dioxide; SIRS, systemic inflammatory response; V-Q, ventilation perfusion scan; TEE, transesophageal echocardiography; ECG, electrocardiogram; V, Fib-ventricular fibrillation; MI, myocardial infarction; PaO₂, partial pressure of oxygen; FiO₂, fraction of inspired oxygen; O₂, oxygen; wbc, white blood cells; ml, milliliter.