

Pilot study on the impact of ERAS protocol adherence on complications and readmissions following open radical cystectomy. Experience from an ERAS® Society qualified Center

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Abstract

Objectives

This pilot study evaluated the impact of Enhanced Recovery After Surgery (ERAS) protocol adherence on postoperative outcomes following open radical cystectomy (RC), with a focus on complications and readmissions.

Methods

The ERAS® RC pathway (20 items) was implemented at our ERAS®-qualified centre (AO Santa Croce e Carle) from October 2019. Prospective perioperative data were collected for the first 100 consecutive patients. Outcomes included in-hospital, 30- and 90-day complications and readmissions. Adherence $\geq 70\%$ was defined as good compliance. Logistic regression assessed associations between adherence and outcomes. The primary endpoint was ERAS adherence versus early complications; the secondary endpoint was 90-day readmissions and their predictors.

Results

Most patients were male (88%), with a mean age of 72.2 ± 7.9 years; 95% underwent RC for oncologic indications. Mean length of stay (LOS) was 10.5 ± 7.2 days. Within 30 days, 63% experienced complications, predominantly Clavien-Dindo grade II; urinary tract infections were the most frequent (40%). Readmission rates were 17% at 30 days and 12% at 90 days. ERAS adherence was high preoperatively (95.5%) and intraoperatively (99.2%), but lower postoperatively (65.8%). Adherence $> 70\%$ was significantly associated with shorter LOS ($p = 0.001$) and fewer 30-day complications ($p = 0.012$). ERAS adherence was the only independent predictor of reduced in-hospital ($p = 0.0004$) and 30-day complications ($p = 0.001$). No significant association with 90-day readmissions was observed.

Conclusions

High ERAS adherence, particularly during the postoperative phase, significantly improves early outcomes after open RC, reducing complications and shortening hospital stay. These findings support structured ERAS implementation with continuous adherence monitoring, and warrant multicenter validation across both open and minimally invasive approaches.

Introduction

Radical cystectomy (RC) with pelvic lymph node dissection (PLND) and perioperative chemotherapy currently represents the standard of care for recurrent high-risk non-muscle-invasive and muscle-invasive bladder cancer [1]. Open RC represents a significant surgical challenge in urology, featuring both

a resective and a reconstructive component, often involving bowel manipulation and anastomosis. However, RC is notoriously associated with significant morbidity [2], partly due to the characteristics of patients, who are frequently affected by multiple comorbidities [3]. Enhanced recovery after surgery (ERAS) programs were initially introduced in colorectal surgery to reduce surgical stress and facilitate postoperative recovery, showing fewer complications and shorter length of stay (LOS) [4, 5]. ERAS is a multidisciplinary care pathway designed to standardize and improve perioperative management, involving preoperative, intraoperative, and postoperative interventions. In the field of urology, patients undergoing RC seem to be the best candidates to follow the ERAS protocol. In 2013, the ERAS® Society released guidelines for perioperative care after RC [6], including 20 strongly recommended items. Nevertheless, there are substantial differences among published protocols regarding specific ERAS measures following RC [7, 8]. Data suggest that increased compliance with core elements is associated with improved outcomes across surgical specialties [9–12]. However, while ERAS protocols are widely recommended and increasingly adopted, the specific impact of adherence—particularly during the postoperative phase—remains poorly defined in patients undergoing open radical cystectomy (RC). Therefore, we conducted a prospective observational study to evaluate the association between ERAS adherence and postoperative outcomes, with a focus on complications and readmissions.

Materials and methods

All consecutive patients undergoing open RC were asked to participate in a prospective observational trial, between October 2019 and May 2024. All patients were treated at the Department of Urology, AO Santa Croce e Carle (HUB Center for the Province of Cuneo, Italy), ERAS® Society-Qualified Centre from October 2019. Inclusion criteria included patients undergoing open RC who participated in the enhanced recovery protocol. Exclusion criteria were inability or unwillingness to adhere to the enhanced recovery protocol. The RECOVer Checklist was followed while drafting this manuscript [13]. Data were recorded and stored in the ERAS® Interactive Audit System (EIAS) database. The trial was conducted according to the Declaration of Helsinki and informed consent was obtained by all the patients involved in the study. The study was conducted in accordance with the Declaration of Helsinki. Data were prospectively collected within an Ethics Committee-approved observational bladder cancer quality improvement program. Written informed consent was obtained from all participants.

ERAS protocol for radical cystectomy

The ERAS® society Guidelines for perioperative care after RC were followed [7], considering the 20 strongly recommended single items⁶. The two weakly recommended items - omission of resection site drainage and early removal of urinary drainage - were not taken into account.

Preoperative ERAS Interventions

The ERAS protocol included the following preoperative interventions: counseling by the ERAS team (urologist, dedicated anesthesiologist, nurse, specialized stoma care nurse), optimization of medical

conditions, nutritional support, smoking and alcohol cessation support 4 weeks before surgery, and encouragement of physical activity. Carbohydrate loading was administered 12 and 2 hours before surgery, with no bowel preparation. Clear liquids and solids were allowed up to 2 and 6 hours prior to surgery, respectively. No long-acting sedatives were used for premedication. Thrombosis prophylaxis included compression stockings and pharmacologic prophylaxis with low-molecular-weight heparin.

Intraoperative ERAS Interventions

Open radical cystectomy was performed using a reduced incision (subumbilical-pubic, < 20 cm in length) following skin preparation with chlorhexidine-alcohol. Urinary diversion included orthotopic neobladder, ileal conduit according to Bricker, and ureterocutaneostomy. Orthotopic neobladder types included mostly Y-shaped (77%), or Camey II and VIP, based on the surgeon's preference (Tab 1). Standard antibiotic prophylaxis included 2 g of cefazolin 1 hour before incision and 1 g after 3 hours. Routine use of nasogastric tubes postoperatively in the operating room was avoided. The anesthetic protocol included epidural catheterization and systemic medications, avoiding long-acting opioids. Airway monitoring was performed via an endotracheal tube, with continuous depth-of-anesthesia monitoring and forced-air warming for the upper body.

Postoperative ERAS Interventions

During postoperative days (POD) 0–4, bowel stimulation was encouraged using chewing gum or coffee. Oral laxatives (Macrogol 13.8 g) were administered twice daily starting on POD 0, and an unrestricted diet was implemented. Early mobilization was promoted by dedicated nursing staff, and daily oral nutritional supplements were provided. Mobilization goals were >1 hour on POD 1, >2 hours on POD 2, and >4 hours on POD 3. Nutritional intake targets were >300 kcal on POD 1 (1 bottle = 151 kcal), >600 kcal on POD 2, and >600 kcal on POD 3. Intravenous fluid administration was limited to <3500 mL on POD 0 (including intraoperative fluids), with total infusion duration limited to <5 nights. Weight variation on POD 1 was targeted at <2 kg.

Discharge Criteria

Discharge criteria were predefined as follows:

- Ileal conduit and ureterocutaneostomy: regular solid diet, normal bowel movements, no signs of active infection, independent stoma management.
- Orthotopic ileal neobladders: regular solid diet, normal bowel movements, and no signs of active infection. Initially, patients with orthotopic urinary diversion remained hospitalized until removal of ureteral stents and Foley catheters (neobladder contrast imaging on POD 12). Subsequently, discharge was expedited.

Study Design

Patients' characteristics (age, sex, body mass index - BMI, American Society of Anesthesiologists - ASA score, Charlson Comorbidity Index - CCI, diabetes, previous pelvic-abdominal surgeries, prior pelvic radiotherapy), preoperative characteristics (hemoglobin – Hb, creatinine, estimated glomerular filtration rate – eGFR, malnutrition, pathological and clinical stage and grade of bladder disease, histological findings, neoadjuvant chemotherapy – NAC), and intraoperative data (operative time, type of surgery and urinary diversion, blood loss, anesthesia type) were collected for all participants.

Data on ERAS protocol adherence and recovery parameters - in-hospital complications, complications within 30 and readmission within 90 days - were recorded and stored in the ERAS® Interactive Audit System database. Follow-up data were collected during outpatient visits and emergency department admissions. Based on the ERAS previous evidence, threshold for good adherence to protocol was determined as >70% adherence to postoperative ERAS elements [5]. Complications were classified according to the Clavien-Dindo classification.

Evaluation criteria

The primary endpoint was to evaluate the association between adherence to ERAS parameters and early postoperative complications, both in-hospital and within 30 days. The secondary endpoint was to assess the association between adherence to ERAS and readmission rates within 90 days, along with potential predictors.

Statistical analysis

Data distribution was verified using the Shapiro-Wilk test, and data were described and presented through median and interquartile range (IQR) for continuous variables, mean $\pm$ standard deviation for parametric variables, and through frequencies (proportions) for categorical variables. Statistical analyses included Chi-square testing to evaluate the impact of the 70% adherence threshold on in-hospital outcomes, 30-day complications, and 90-day readmissions. Clinical parameters, intraoperative and postoperative characteristics were compared between participants with more or less than 70% of adherence with the Mann–Whitney test and Fisher Exact Test, as indicated. Fisher's exact test was used to assess potential confounders. Multivariate logistic regression (MVA) was conducted using ERAS adherence as the primary independent variable, adjusting for age, ASA, CCI. Statistical significance was defined as $p < 0.05$. All analyses were performed using R software (R Development Core Team).

Results

The first 100 patients enrolled after ERAS® qualification were prospectively included. Most patients were male (88%, $n = 88$), with a mean age of 72.2 ± 7.9 years. The majority underwent RC for oncological reasons (95%). Intraoperative complications occurred in 14 patients (14%), almost all related to the need for red blood cell transfusion (12 cases – 85.7%). The mean length of stay (LOS) was 10.5 ± 7.1 days, with a median of 8 days (IQR 6.00–13.00). Patient and perioperative characteristics are reported in (Table 1).

Adherence to the ERAS protocol was very high in the preoperative (95.46 ± 9.39) and intraoperative phases (99.22 ± 4.37), but lower in the postoperative phase (65.77 ± 15.59) (Table 2).

In-hospital and 30-day complications and readmissions

A total of 63 patients (63%) experienced at least one complication within 30 days of surgery, including both in-hospital and post-discharge events. The majority of complications were Clavien-Dindo grade II (81%), with urinary tract infections being the most common. Seventeen patients (17%) required hospital readmission within 30 days (Table 2).

90-day complications and readmissions

At 90-day follow-up, at least one postoperative complication occurred in 59 patients (59%), with 83% classified as Clavien-Dindo grade II. In four cases, complications were grade IIIa (percutaneous drainage of fluid collections), and one patient experienced a grade IIIb complication (rectal perforation). Two patients had grade IVa complications requiring ICU admission, and one patient died (grade V) due to recurrence of ileo-ileal anastomotic dehiscence and septic shock.

At 90 days postoperatively, 11 patients (12%) had been readmitted. Of these, five experienced grade II complications, while another five developed grade IIIa complications. One patient died (grade V) due to perforation of an esophageal ulcer (Table 2).

At the 90-day mark, 92 patients (92%) were alive; one patient (1%) had died due to bladder cancer progression, and four (4%) from unrelated causes.

Impact of ERAS Adherence on Outcomes

Using a 70% adherence threshold, a statistically significant association was observed between higher adherence and a reduced rate of in-hospital postoperative complications (Chi-square test, $p < 0.0011$), as well as a lower rate of complications at 30 days ($p < 0.0119$). (Table 4)

No statistically significant difference was observed for 90-day readmissions at this threshold.

To assess whether patients achieving $\geq 70\%$ adherence differed in baseline characteristics, Fisher's test was performed on ASA and CCI distributions. ASA class approached statistical significance ($p = 0.055$), while CCI differed significantly between groups ($p = 0.018$), with a higher proportion of patients presenting a CCI > 6 among those who did not reach the threshold value. (Table 3)

ERAS adherence was the only independent predictor significantly associated with a reduced risk of in-hospital complications ($p = 0.0004$, OR = 0.93) and 30-day complications ($p = 0.0012$, OR = 0.94) in the multivariate model. Univariate analysis (UVA) indicated a protective effect of ERAS adherence on 90-day readmissions ($p = 0.0445$, OR 0.96). These findings prompted a more focused investigation of the relationship between adherence patterns and late postoperative outcomes.

To this purpose, ERAS adherence was stratified into quartiles. While the lowest quartile (<50%) did not show a significant association with 90-day readmissions, the higher quartiles demonstrated a clear dose–response trend, suggesting a progressively protective effect with increasing adherence. Based on this observation, a transformed continuous variable (ERASp_lin50) was created, coded as 0 for adherence <50% and increasing linearly for values $\geq 50\%$. When evaluated in UVA, ERASp_lin50 showed a significant protective association with 90-day readmissions ($p = 0.0326$, OR = 0.94). In the subsequent multivariate analysis (MVA), ERASp_lin50 retained the same protective direction of effect and approached statistical significance ($p = 0.0548$, OR = 0.95). (Table 5)

Discussion

This prospective observational pilot study investigated the impact of adherence to the ERAS protocol on postoperative outcomes in patients undergoing open RC at an ERAS Qualified Center. Our preliminary findings show that while adherence to preoperative and intraoperative ERAS items was excellent, postoperative adherence emerged as the key determinant of improved outcomes. Accordingly, improving postoperative adherence may represent the most effective and clinically actionable strategy to reduce complications after radical cystectomy. Importantly, higher adherence to postoperative ERAS elements was associated with a significantly lower incidence of postoperative complications, both during the initial hospital stay and at 30-day follow-up. Moreover, good adherence to ERAS was independently associated with reduced complication rates. These initial results suggest a relevant role for ERAS protocol adherence in improving surgical outcomes following open RC. Previous studies in colorectal and gynecologic oncology have demonstrated a strong correlation between ERAS compliance and reduced morbidity, shorter length of stay, and decreased readmission rates [5]. Although ERAS protocols have been progressively adopted in urologic oncology, robust data specifically concerning RC remain limited. ERAS has become a cornerstone in the management of RC, with EAU Guidelines strongly recommending ERAS ("fast-track") measures [1]. Patients treated according to the ERAS protocol have shown fewer complications—such as wound healing disorders, fever, and thrombosis—and better physical functioning scores [14]. Multiple studies on RC have reported benefits in terms of LOS, time to first flatus, and time to regular diet in patients following the ERAS protocol [15–17]. Furthermore, benefits from ERAS seem to be greatest in less fit patients [18,19], leading to better quality of life and reduced costs [20,21].

However, ERAS is a comprehensive protocol: despite the release of the ERAS® Society Guidelines for RC in 2013, only one study has reported outcomes for RC using a standardized ERAS protocol [22]. Moreover, implementation and adherence to ERAS appear to vary considerably [23–25]. On one hand, early postoperative complications are associated with worse survival after major surgery; on the other, increased compliance with ERAS protocols appears to improve outcomes across surgical specialties [10–13].

This pilot study comprehensively evaluated the effect of ERAS adherence on short-term postoperative outcomes in a cohort undergoing open RC, using standardized recommendations and data collection

through the ERAS Audit System. Higher postoperative adherence to ERAS was associated with a lower incidence of postoperative complications, both during the hospital stay and at 30-day follow-up, and was independently associated with a reduction in complication rates. It is hoped that the encouraging results of this pilot study will foster interest in validating these findings through multicenter studies, encompassing both open and minimally invasive surgical approaches.

Limitations

This pilot study presents several limitations. First, its single-center nature. Second, as a pilot study, the limited sample size—although sufficient for our primary endpoint—is likely underpowered to detect secondary outcomes. Moreover, no comparison with a control group, not even a historical one, was possible due to the lack of available data. All patients in this cohort underwent open surgery; therefore, these findings cannot be generalized to minimally invasive RC. While the adoption of the robotic approach has rapidly increased [26], evidence supporting its superiority over open surgery remains limited [27]. Furthermore, open RC still accounts for a substantial proportion of all RC compared to minimally invasive approaches [26]. Additionally, most procedures were performed by a single high-volume surgeon, which may limit generalizability but also reduces operator-related variability.

Despite these limitations, these encouraging initial results support efforts to maximize adherence to the ERAS protocol, allowing patients to benefit from a care pathway characterized by full coordination among urologists, anesthesiologists, and nursing staff.

This prospective pilot study demonstrates that high adherence to the ERAS protocol is associated with a significant reduction in early postoperative complications and shorter hospital stay in patients undergoing open RC. While preoperative and intraoperative compliance was consistently high, postoperative adherence emerged as the key determinant of improved outcomes. ERAS adherence was the only independent predictor of reduced in-hospital and 30-day complications. These findings support the importance of structured ERAS implementation and continuous adherence monitoring, and they highlight the need for multicenter studies to validate these results across different surgical settings and approaches, both for open and minimally invasive RC.

Conclusion

High adherence to ERAS protocol, particularly during the postoperative phase, is associated with improved early outcomes after open radical cystectomy, including reduced postoperative complications and shorter length of stay. Postoperative adherence appears to represent the main modifiable determinant of perioperative outcomes, highlighting the importance of targeted strategies to optimize compliance in this phase. These findings support structured ERAS implementation with continuous adherence monitoring and warrant validation in larger multicenter studies, including both open and minimally invasive approaches.

Abbreviations

ERAS - Enhanced recovery after surgery

LOS - Length of stay

RC - Radical cystectomy

Declarations

Conflict of interest: The authors declare no conflict of interest.

Approval of the research protocol by an Institutional Review Board: This study was conducted in accordance with the principles of the Declaration of Helsinki. Data were prospectively collected within a bladder cancer quality improvement program approved by the local Ethics Committee (approval date: 29 June 2022; local authorization date: 28 July 2022). Written informed consent was obtained from all participants prior to inclusion.

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Author Contribution

IM: Conceptualization, supervision, patient recruitment, surgery, data interpretation, manuscript review and final approval. LO: Data collection, statistical analysis, data interpretation, manuscript drafting, manuscript revision and final approval. EA: Data interpretation, manuscript drafting and critical revision. FB: Statistical analysis, methodology and critical revision. SP: Anesthesiology protocol development, perioperative management and manuscript review. MC: Anesthesiology protocol development, perioperative management and manuscript review. GB: Data collection and manuscript review. PIO: Data collection and manuscript review. CB: Data interpretation and manuscript review. ED: Data collection, protocol development and manuscript review. All authors read and approved the final manuscript. IM and LO contributed equally to this work and share first authorship.

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Tables

Tables 1 to 5 are available in the Supplementary Files section.

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