Evaluation of an enhanced recovery protocol on patients having radical cystectomy for bladder cancer

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Abstract

Introduction: Enhanced recovery after surgery (ERAS) protocols are multimodal perioperative care protocols that are designed to shorten recovery time and reduce complication rates.[1,2] An ERAS protocol was implemented in the Saskatoon Health region for radical cystectomy patients in 2013. This study evaluates the safety and efficacy of the protocol for patients having radical cystectomy for bladder cancer.
Methods: Length of stay, early in-hospital complication rates, 30-day readmission rates, age, and gender were collected for patients seen for bladder cancer requiring radical cystectomy in Saskatoon between January 2007 and December 2016. Of these patients, 176 were pre-ERAS implementation (control group) and 84 were post-ERAS implementation (experimental group). The data from each variable was compared between the groups using a Z-test.
Results: There was no significant difference in age or gender of patients between the groups. Average length of stay pre-ERAS was 14.25±14.57 days, which is significantly longer than the post-ERAS average of 10.91±8.56 days (p=0.043). There was no significant difference in 30-day readmission rate (19.87% pre-ERAS vs. 19.05% post-ERAS; p=0.873) or complication rate (51.7% pre-ERAS vs. 46.4% post-ERAS; p=0.425).
Conclusions: The implementation of an ERAS protocol for radical cystectomy reduces length of stay, with no effect on early complication rates or 30-day readmission rates. This indicates that the protocol is safe for patients when compared to previous practices and is an effective means of reducing length of stay.

Introduction

Enhanced recovery after surgery (ERAS) protocols are multimodal perioperative care protocols that are designed to reduce surgical stress response and improve health outcomes in surgical patients.[1] ERAS protocols are designed to shorten recovery time by focusing on key pre-operative, operative, and post-operative elements.[1,2] This includes items such as preoperative counselling, preventing intraoperative hypothermia, optimization of nutrition, and early mobilization.[3] ERAS protocols were first developed in the 1990s for colorectal cancer surgeries, where they have proven effective in reducing length of stay in-hospital, with varying effects on complication rates.[3–5] They have also been applied to vascular surgery and thoracic surgery, and more recently have expanded to patients undergoing radical cystectomy procedures.[1]

Radical cystectomies with lymph node dissection are the gold standard treatment for patients with muscle invasive bladder cancer, and are associated with some of the worst morbidity and complications rates of all urological procedures.[1,6] Patients that require a radical cystectomy are often elderly patients with comorbidities, and could therefore greatly benefit from protocols that reduce surgical complication and stresses.[2] Due to the relatively recent introduction of ERAS protocols to radical cystectomy procedures, the literature on the effectiveness of ERAS on radical cystectomy outcomes is limited.[7] Elements of ERAS that are effective for colorectal cancer surgery may not be as effective in bladder cancer surgery. It has been previously suggested that further study is required to determine which elements would be beneficial to include and if the modified ERAS protocols can be equally effective in bladder cancer patients.[2] Although there is a great deal of variation in the outcomes of ERAS in the context of cystectomy in the current literature, overall, the majority of studies that have been conducted have shown promising results in terms of reduced length of stay and reduced morbidity.[2,7-13]

In 2013, the Saskatoon Health Region implemented its own ERAS protocol, called the Radical Cystectomy/Ileal Conduit Clinical Pathway. The protocol was developed through collaboration between anesthesia, urology, home care, enterostomal therapists, physiotherapy, pre-admission nurses, recovery ward nurses, nurse navigators and nurse educators, and pharmacists. It contains 17 of the 22 elements recommended in the ERAS® Society Guidelines *(Table 1)*.[2] The pathway is under the oversight of a urologist, however the nursing staff can make adjustments and are responsible for documenting adherence to the guidelines.

The primary objective of this study was to evaluate the effectiveness of the Radical Cystectomy/Ileal Conduit Clinical Pathway ERAS protocol, using length of stay, post-operative complications, and 30-day readmission rate parameters.

Methods

After obtaining ethics exemption (reference REB: BIO-17-11), we retrospectively collected demographic and clinical data for all patients undergoing a radical cystectomy/ileal conduit for bladder cancer between January 2007 to December 2016 in Saskatoon. This generated a cohort of 260 patients (176 patients seen prior to implementation of the pathway and 84 patients seen

after implementation of the pathway). Age, sex, pathological staging, and primary surgeon was collected for all patients. There was a total of 15 surgeons practicing throughout the duration of the study. Data on length of stay, post-operative complications, and 30-day readmission rate were compiled by the Saskatoon Health Region's Strategic Health Information and Performance Support (SHIPS) data collection agency. Retrospective chart review was conducted to collect data on use of neoadjuvant therapy and epidural use. Although there were no standardized criteria for discharge, as it was at the discretion of the most responsible physician (MRP), it typically involved being able to ambulate, and tolerate adequate nutrition and analgesia.

As there was right skewness of the data, the primary outcomes of length of stay was analyzed using Gamma distribution, where the level of statistical significance was set at alpha=0.05 *(Figure 1)*. Demographic information, pathological staging, post-operative complication rates, and 30-day readmission rates between the pre-ERAS and post-ERAS groups were analyzed using a Z-test, where the level of statistical significance was set at Z=1.96, alpha=0.05 (two-tailed).

Results

Demographics and cohort characteristics

There was no significant difference in age or gender between the two cohorts. *(Table 2)* 47.6% of patients were from the Saskatoon Health Region, and 42.4% of patients were from more rural areas of Saskatchewan. None of the patients pre-ERAS implementation received neoadjuvant therapy, whereas 16 patients out of 86 of the post-ERAS cohort received neoadjuvant chemotherapy. Data for epidural use prior to ERAS implementation was not available. After ERAS implementation, there were 72 patients out of 86 who received epidurals (83.7%). There was not always clear documentation for why an epidural was not used, but some documented reasons included spinal deformity, or paraplegia not necessitating epidural use.

234 patients underwent complete lymph node dissection, which involved taking the internal and external iliac lymph nodes and obturator lymph nodes, with the superior limit being the bifurcation of the aorta. 23 patients underwent incomplete lymph node dissection, which was at the discretion of the surgeon. TNM pathological staging showed no significant differences in pre and post-ERAS for stages 0is through 3b, however there was a significant difference in pre and post-ERAS 4b staging (7 patients pre-ERAS vs. 0 patients post-ERAS, p=0.007). *(Table 3)*

Data on ASA score and pre-operative nutritional status was not available for all patients.

Length of stay

The mean length of stay prior to ERAS implementation was 14.25±14.57 days, with a median of 10 days. The mean length of stay after ERAS implementation was 10.91±8.56 days, with a median of 9 days. The mean length of stay prior to ERAS was significantly longer (p=0.043). *(Figure 2, Table 4)*

Complication rates

There was no significant difference in early in-hospital complication rates (51.7% pre-ERAS vs. 46.4% post-ERAS, p=0.425). The most commonly identified complications were ileus, urinary tract infection (UTI), non-UTI infection, and wound dehiscence. There was no significant difference when comparing pre-ERAS and post-ERAS rates for any of the individual complications identified *(Table 5).*

30-day readmission rates

In the timeframe of this study, there were 49 readmissions, 35 prior to ERAS implementation, and 16 after implementation. This represents a 30-day readmission rate of 19.87% and 19.05% before and after ERAS implementation (p=0.873). The average readmission rate was 5.5 per year pre-ERAS compared to 4 post-ERAS, representing a non-statistically significant difference (p=0.104). The most common cause of readmission in both cohorts was infection (UTI and non-UTI infection) *(Table 6)*. Causes for readmission are listed in Table 7.

Compliance data

After implementation of the ERAS protocol in January 2013, all patients undergoing radical cystectomy for bladder cancer were placed on the protocol, representing a 100% compliance rate.

Discussion

Adoption of ERAS protocols is slow among urologists, many of whom are not convinced it works, or that there is not enough evidence to support its implementation.[14,15] However, with the growing body of evidence showing the benefit of ERAS in cystectomy, it is becoming harder to dispute that ERAS results in better patient outcomes. Our study is the first to evaluate ERAS protocols for radical cystectomy in a Canadian context, where our high percentage of patients from a rural setting creates a unique challenge for care, differing from American and European studies. In addition, our series of radical cystectomy patients utilizing an ERAS protocol implements 17 out of 22 ERAS elements, which is the most of any study performed to date, with the added strength of having a 100% compliance rate.[14] When compared to a retrospective cohort, we have shown that and an ERAS protocol in this population is effective in reducing LOS, with no change on post-operative complications or readmissions rates. This is consistent with many other studies, although there is a high degree of variation in study outcomes.[7] Studies by Djaladat et al., Mukhtar et al., Daneshmand et al., and more recently Baack et al., found similar results.[5,16–18] It is also reassuring to see a downward trend in the complication rates for overall complications, and more specifically for 3 of the most common complications (ileus, non-UTI infections, and wound dehiscence).

The benefits of ERAS are not only confined to LOS, complication rates, and readmission rates. One study found that it also had a positive effect on emotional function, resulted in less fatigue, and better cognitive and physical functioning at discharge.[19] The economic impact on the system is another major factor to consider. In the colorectal world, it's been estimated that there

is a cost savings of $6,900 per patient who undergoes ERAS compared to traditional peri-operative orders.[1] Furthermore, it's been shown that even though patients are getting discharged out into the community more quickly, the costs are not transferred into the community in the form of more emergency room or practitioner visits, and do not result in a lower quality of life.[1] In fact, medical and indirect non-medical costs were significantly lower in areas where ERAS was implemented. ERAS can also greatly reduce variation between institutions by providing a standardized care plan for patients, which may be another factor affecting LOS.[7,20] In the UK, some institutions report a 3-fold variation in LOS, with the longest average LOS being 29 days.[13] As there are a multitude of factors at play in ERAS implementation, it is difficult to identify specific elements that affect LOS; it is possible that the decrease in LOS is also due to standardization in practice and documentation in addition to the intervention itself.

The challenge becomes then, what elements of ERAS to include, as not all ERAS guideline recommendations, originally intended for colorectal surgery, may have a beneficial effect for cystectomy patients. Many studies lack information regarding elements of ERAS included, and compliance with the elements.[21] Even when included, due to the multivariate and complex nature of these pathways, it is very difficult to assess the individual contribution of each element of ERAS to the overall outcome.[8] While there are studies that look at individual ERAS elements in the context of cystectomies, such as chewing gum[22] or the use of non-opioid vs. opioid analgesics,[23] most of the reasoning behind elements included in ERAS are either from studies done in colorectal surgery, or based on physiological reasoning.[3,7,10,12,14,20,24,25]

Only a minority of ERAS for radical cystectomy studies have protocols that implement more than half of the recommended principles, and no studies have implemented all 22 ERAS elements.[2,14] Although the systematic review by Nicholson et al. found that including more elements does not always translate into better outcomes,[8] there is no evidence in the literature to suggest that any of the elements included in the Radical Cystectomy/Ileal Conduit Clinical Pathway would be detrimental to cystectomy patients.[2,3] With regards to the 5 elements omitted from our pathway, the evidence for omitting the pelvic drain is weak, and based on colorectal surgery evidence; in cystectomies, the risk of urinary leak may be higher, and thus having the drain may be beneficial.[3] Similarly, leaving a urethral drain may be beneficial in colorectal cancer, but is not necessary in cystectomy patients. Our center does not routinely perform laparoscopic cystectomies, and the evidence in favour of robot assisted cystectomy is still in the trial phase. There may be a role for having standardized protocols for perioperative anesthesia, however in Saskatoon, there is a lack of consensus from anesthesiologists on how anesthetics are delivered. Similarly, a lack of consensus from MRPs on nausea and vomiting medications is also a barrier to a standardized nausea and vomiting prophylaxis protocol. These two areas merit further exploration by the ERAS protocol team, with the hopes that standardized protocols can be implemented at our center.

Other future directions include exploring different analgesic methods, increased education with healthcare staff, and the use of drugs such as alvimopan. Studies have shown the

benefits of rectus sheath blocks over epidurals, the benefits that alvimopan can have on LOS and time to flatus, and improvements in outcomes with increase healthcare staff education.[13,14,23] Having a pathway with 100% compliance allows for potentially randomized-controlled trials looking at specific elements such as these.

Limitations

One of the major limitations of this study is that it is a retrospective study, comparing a more current cohort of patients with a historical group. This may be problematic as the culture around patient-centered care and outcomes has shifted. Additionally, there is no documentation showing which elements of ERAS may have already been practiced prior to official implementation of ERAS. There is also the added consideration of number and skills of surgeons involved, techniques and technology that are improving, and changes in treatment practices over time. For example, neoadjuvant therapy is being adopted more frequently, particularly after implementation of ERAS protocols, and the impact of neoadjuvant therapy on outcomes is not fully known. Similarly, epidural use for pain control was very common in our protocol, but the rates of epidural use prior to ERAS implementation is unknown. The retrospective nature of the study also limited data collection for factors such as pre-op nutritional status and ASA score, or post-operative oral intake and first day of stool passage, which was not always recorded in the charts. Furthermore, the study is non-randomized, although a randomized control trial of ERAS as a whole in the present day would nearly impossible, and possibly unethical given the body of evidence in favour of ERAS. Finally, much of the data was only available through the provincial database, limiting the availability and form of some of the data. For example, only 30-day readmission rates were available, although it is known that 90-day readmission rates are a better reflection of long-term outcomes of ERAS. This also limited classification of complications using commonly used methods such as Clavian Dindo scoring.

Conclusion

Our study adds to the growing body of evidence showing that ERAS protocols decrease length of stay. The implementation of an ERAS protocol for cystectomy has no effect on early post-operative complication rates or 30-day readmission rates when compared to previous practices, indicating that the protocol is safe for patients while being an effective means of reducing length of stay. Further consideration needs to be given to assessing the benefits of specific ERAS elements in the setting of radical cystectomy, as further data will direct adjustments made to the Radical Cystectomy/Ileal Conduit Clinical Pathway. Reducing length of stay may translate into improved patient outcomes and decreased healthcare system costs, which may be an area of further research.

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Figures and Tables

Fig. 1. There was a right skewness in length of stay in both the pre-ERAS and post-ERAS cohorts (skewness of 4.25 and 1.91, respectively). ERAS: enhanced recovery after surgery.

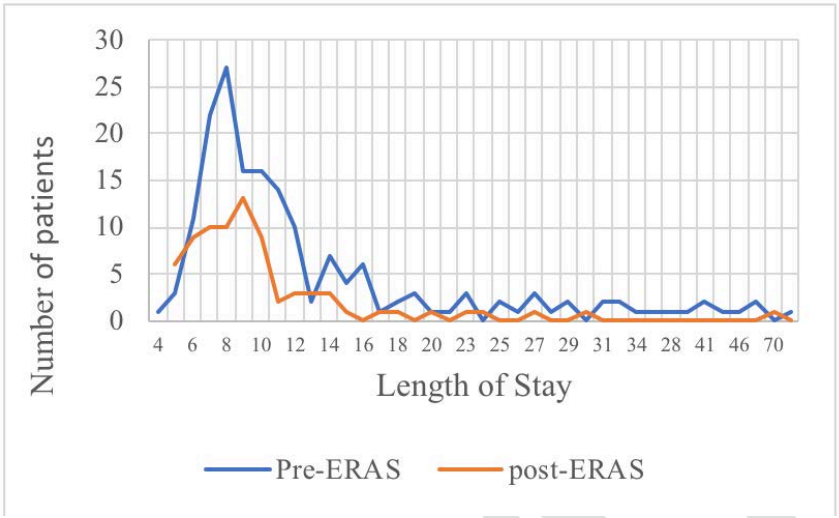

Fig. 2. There was a significant difference in mean length of stay when comparing pre-ERAS implementation cohorts with post-ERAS (14.25±14.57 days vs. 10.91±8.56 days, respectively; p=0.043). ERAS: enhanced recovery after surgery.

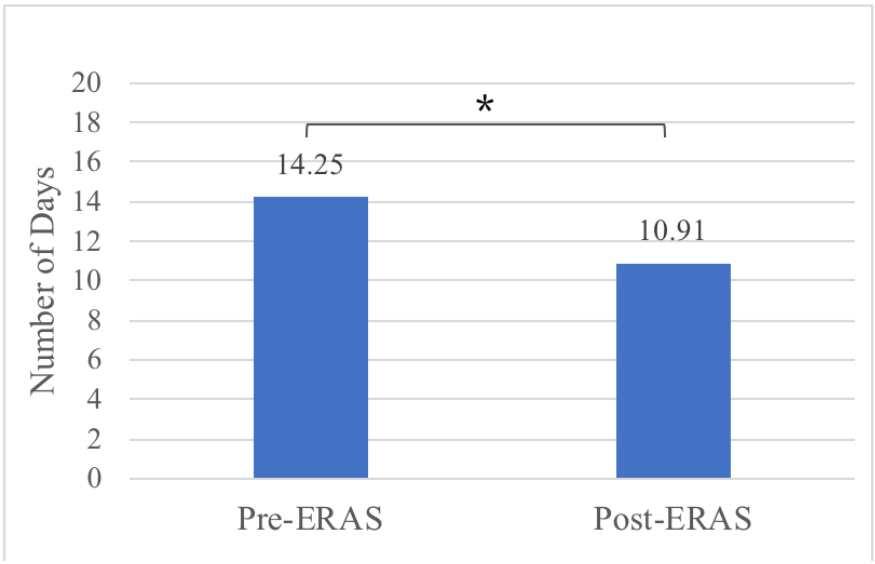

Table 1. ERAS element summary and inclusion		
ERAS element	**Summary**	**ERAS® society grade of recommendation**
Included elements		
1. Preoperative counselling and education	Patients meet with a nurse navigator and urologist prior to procedure to receive counselling on procedure and manage expectations	Strong
2. Preoperative medical optimization	Includes elements such as smoking cessation, weight loss or gain as required, control of comorbidities	Strong
3. Oral mechanical bowel preparation	Traditional bowel preparation prior to surgery is no longer required	Strong
4. Preoperative carbohydrate loading	Increased intake of carbohydrates prior to surgery in non-diabetic patients	Strong
5. Preoperative fasting	Solid foods are allowed up to 6 hours prior to general anesthesia, and clear fluids allowed up to 2 hours prior	Strong
6. Thrombosis prophylaxis	Pharmacologic prophylaxis with LMWH prior to surgery, compression stocking use, and extended prophylaxis post-surgery as indicated based on patient risk	Strong
7. Epidural analgesic	Thoracic epidural placement prior to surgery for pain management in lieu of increased opioid use	Strong
8. Antimicrobial prophylaxis and skin preparation	Single dose of antimicrobial prophylaxis 1 hour prior to skin incision, and skin preparation with chlorhexidine-alcohol preparation	Strong
9. Perioperative fluid management	Fluid balance optimization using cardiac output as a guide to avoid over- and dehydration.	Strong
10. Preventing intraoperative hypothermia	Maintain normal body temperature during and postoperatively with warmed fluids and forced air patient warming	Strong
11. Nasogastric intubation	Avoid the use of postoperative nasogastric intubation	Strong

12. Prevention of postoperative ileus	Optimize gastrointestinal function through a multimodal approach, including oral magnesium, chewing gum, and early mobilization	Strong
13. Postoperative analgesia	Post-operative analgesia including thoracic epidural and oral medication for breakthrough pain	Strong
14. Early mobilization	Patients should be encouraged to mobilize immediately after surgery	Strong
15. Early oral diet	Oral nutrition to be initiated on postoperative day 0	Strong
16. Pre-anaesthesia medication	Avoid the use of long acting sedatives	Strong
17. Audit	Monitoring for compliance with ERAS protocol	Strong
Excluded elements		
18. Minimally invasive approach	Use of laparoscopic/robotic technique	Strong
19. Resection site drainage	Omission of the use of perianastomotic and/or pelvic drain	Weak
20. Standard anesthetic protocol	Anesthetic protocols in place to ensure hemodynamic stability, muscle relaxation, proper anesthesia depth, appropriate analgesia	Strong
21. Urinary drainage	Removal of transurethral catheter on postoperative day 1 after pelvic surgery in patients with low risk of urinary retention	Weak
22. Prevention of postoperative nausea and vomiting	Prophylactic multimodal approach to prevent nausea and vomiting in patients at risk	Strong

ERAS: enhanced recovery after surgery; LMWH: low molecular weight heparin.

Table 2. Demographics			
	Pre-ERAS	**Post-ERAS**	**p**
Age	67.84	68.9	0.449*
Male (%)	72.16	82.14	0.063+

*The difference in age was non-significant (p>0.05). +The difference in proportion of males was non-significant (p>0.05). ERAS: enhanced recovery after surgery.

Table 3. Pathological staging			
	Pre-ERAS	**Post-ERAS**	**p**
Complete lymph node dissection (%)	92.05	89.29	0.484*
Stage 0is	13.64	17.86	0.391+
Stage 1	11.36	10.71	0.875+
Stage 2	22.16	15.48	0.184+
Stage 3a	32.95	39.29	0.323+
Stage 3b	15.91	16.67	0.878+
Stage 4a	0	0	0
Stage 4b	0.040	0	0.007

*The difference in completed (vs. incomplete) lymph node dissection was non-significant (p>0.05). +The difference in pathological TNM staging was non-significant (p>0.05). Staging based on National Comprehensive Cancer Network (NCCN) TNM Staging system for bladder cancer guidelines.

Table 4. Mean LOS (days), calculated based on gamma distribution			
	Pre-ERAS	**Post-ERAS**	**p**
Mean LOS	14.25	10.91	0.043

ERAS: enhanced recovery after surgery; LOS: length of stay.

Table 5. Complication rate			
Complication	**Pre-ERAS rate (%)**	**Post-ERAS rate (%)**	**p**
Overall	51.7	46.4	0.425*
Ileus	27.8	20.2	0.17*
Infection – non-UTI	10.2	7.1	0.394*
Infection – UTI	2.3	6.0	0.192*
Dehiscence	6.3	4.8	0.614*

*The difference in complication rates was non-significant (p>0.05). ERAS: enhanced recovery after surgery; UTI: urinary tract infection.

Table 6. 30-day readmission rate			
	Pre-ERAS	**Post-ERAS**	**p**
Readmission rate (%)	19.87	19.05	0.873*
Average number of readmitted patients per year	5.5	4	0.104+

*The difference in readmission rates was non-significant (p>0.05). +The difference in average number of readmitted patients per year was non-significant (p>0.05). ERAS: enhanced recovery after surgery.

Table 7. Causes for readmission	
Cause for readmission	**Number of cases**
UTI	9
Non-UTI cause of infection	7
Sepsis	7
Ileus	6
Acute renal failure	4
Malaise and fatigue	3
Tubule-interstitial nephritis	3
Dehydration	2
Other	8
Total	49

Compiled causes for readmission for pre- and post-ERAS. ERAS: enhanced recovery after surgery; UTI: urinary tract infection.