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Comparison of Perioperative Outcomes for Epidural versus Intravenous Patient-Controlled Analgesia after Radical Cystectomy

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Abstract

Background and Objectives—Use of patient-controlled epidural analgesia after various operations has been associated with earlier return of bowel function and thus decrease the length of stay (LOS). The primary aim of this study was to compare LOS after radical cystectomy between patients who received epidural analgesia versus those who received intravenous patient controlled analgesia. Our secondary analysis included the assessment of other metrics such as total opioid requirements, pain scores, return of bowel function and complication rates between the two groups.

Methods—We conducted a retrospective review using the electronic medical records of 308 patients who underwent radical cystectomies at Memorial Sloan Kettering between 2006 and 2011. We aimed to understand if epidural analgesia was associated with a reduced length of stay compared to patient controlled intravenous opioid analgesia. We also aimed to identify performance improvements as a function of epidural analgesia status using various metrics such as pain management, bowel function return, and complication rates. We used both univariate and multivariable analyses to identify if epidural analgesia was associated with meaningful differences in the aforementioned metrics.

Results—Median age at radical cystectomy, body mass index, sex, ASA score, and T stage were similar for both groups. For our primary objective of LOS, we found no significant difference between the two cohorts (8 vs 7 days, $p=0.2$). Analysis of our secondary outcome measures revealed that epidural analgesia use was associated with less total opioid requirement for the first three post-operative days ($p=0.0001$). Additionally, epidural analgesia was found to be associated with improved post-operative pain scores compared to intravenous patient-controlled analgesia on post-operative days 1 ($p=0.0001$) and 2 ($p=0.004$), and there was a slight improvement on post-

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operative day 3, but this was not significant ($p=0.77$). In contrast, we found no difference between pain management types with regard to proportion of patients who experienced delay in gastrointestinal recovery, fluid bolus requirements within the first 3 perioperative days, rates of infection, pulmonary, and complications grade 3.

Conclusions—We have demonstrated that despite significant improvements in initial pain control and less opioid requirement with patient-controlled epidural analgesia, there was no association between analgesic approach and LOS, return of bowel function, or complications.

Keywords

Urinary bladder neoplasms; complications; radical cystectomy; analgesia; patient-controlled; urinary diversion

Introduction

Pain management after major abdominal surgery is important for limiting complications and helping patient recovery. Insufficient pain control can have detrimental effects on the cardiovascular, respiratory, and endocrine systems [1, 2]. Furthermore, inadequate pain control, nausea, and delay in gastrointestinal recovery have all been linked to prolonged hospitalization and to increased costs [3]. Intravenous patient-controlled analgesia (IV PCA) has been considered the standard of care for pain management after major abdominal surgery [4–6]. The ability for patients to administer the amount of opioids based on their own pain threshold makes IV PCA a favorable choice. Studies have shown that IV PCA use is more effective and decreases the risk of pulmonary complications when compared to conventional oral opioid treatment [6, 7].

Patient-controlled epidural analgesia (PCEA) is also commonly used for postoperative pain management. Multiple studies, including randomized prospective trials, have linked the use of PCEA to improved patient pain scores, decreased rates of respiratory failure, earlier ambulation, and improved time to return of bowel function when compared to IV PCA use after thoracic, gynecologic, and general surgical operations [8–12]. Epidural analgesia, when used as part of a multi-modal analgesic regimen, has also been of increased interest for study as part of fast track surgery protocols [13, 14]. The preference to use PCEA after radical cystectomy (RC) versus other analgesic modalities is currently institution and physician specific as there is a relative paucity of data showing a robust difference in patient convalescence when compared to IV PCA. In a small group of consecutively treated patients, Toren et al. observed improvements in pain comfort levels with the use of PCEA but did not note a difference in the extent of postoperative ileus or length of stay (LOS) after RC [15]. Our primary objective was to determine, using both aggregate and time series analysis, if epidural analgesia was associated with a reduction in hospital LOS compared to opioid.

Methods

After institutional review board approval, we performed a retrospective analysis of data obtained for 329 consecutive patients who underwent open RC with bilateral

lymphadenectomy and urinary diversion by a single experienced surgeon (BHB) at MSKCC between 2006 and 2011. While the procedure remained the same throughout the study period, patients were split into 2 cohorts based on postoperative pain management type. IV PCA was used for patients who were treated between 2006 and 2009. In 2009, IV PCA was used for 45 patients while PCEA was used for 6 patients. PCEA was the preferred pain management type for patients treated between 2010 and 2011 unless contraindicated. IV PCA was used for only 3 patients in 2010 and 8 patients in 2011 (Table 1). PCEA was contraindicated in patients who had coagulopathies, significant spine disease, prior surgery, or received anti-coagulation or anti-platelet therapy.

Patients were included only if either PCEA or IV PCA was used for their postoperative pain management. Twenty patients who received both IV PCA and PCEA were excluded from analyses. Complete patient information was missing for one patient leaving 308 patients for evaluation.

Patients receiving IV PCA were given Hydromorphone, Morphine or Fentanyl based on the discretion of the surgical team. All epidural catheters were placed and then managed by the high-volume Acute Pain Service at our institution. The management strategy employed for this bladder cancer cohort had been previously refined on the colorectal and hepatobiliary services. Preoperatively, all epidural catheters were inserted by board certified pain physicians within the vertebral interspaces between T10 and L1. Confirmatory testing was then performed for all epidurals with 3ml of 2% Lidocaine with 1:200,000 Epinephrine. During the study period, we did not have an institutional policy confirming dermatomal sensory loss or a specific definition of an unsuccessful epidural analgesic. Standard dosing was used including: Hydromorphone 8mcg/ml, Bupivacaine 0.05%, 6 ml basal dose with 6 ml on demand at a 30 minute lockout period. Post-operatively, in cases where hydromorphone/bupivacaine combinations were deemed ineffective, the patients were rotated to fentanyl 5mcg/cc with Bupivacaine 0.05%.

Preoperatively, all patients were treated with an identical bowel preparation consisting of two bottles of magnesium citrate over 2 days and a clear liquid diet on the day before surgery. Postoperatively, all patients were managed on an institutional RC urinary diversion care pathway in which oral intake with clear liquid began on postoperative day 2 unless contraindicated by bowel distention or nausea and vomiting. No other major changes, except for change to PCEA, were made to the care pathway during the time periods studied. To identify patients with a delay in bowel function recovery, we retrospectively reviewed all inpatient orders to identify patients who were unable to tolerate diet as per our postoperative care pathway. Patient charts were reviewed in our Electronic Medical Records (EMR) system for those who had a cessation of diet order placed by the covering physician because of the inability to tolerate oral intake. These patients were considered to have delay in bowel function recovery. In such cases, abdominal films were obtained in the perioperative period to assess for ileus and/or bowel obstruction (dilated loops of bowel, absence of air in the rectum and colon) and radiology reports from these studies were used in a dichotomous fashion (presence or absence) to confirm or refute the presence of the aforementioned complications. All medical coding was performed according to the ICD-9 coding registry. Complications occurring within 90-days postoperatively were collected prospectively by

covering physicians in an institutional database and graded based on a modified Clavien-Dindo classification system of surgical complications [16].

Baseline characteristics and crude rates were analyzed with the rank-sum test and chi-square test for continuous and categorical variables, respectively. To assess differences in LOS, return to bowel function, fluid bolus, any post-operative complications, and grade 3 or greater postoperative complications, we built multivariable regression models with pain management type as a predictor. The models were adjusted for age, operating time, estimated blood loss (EBL), American Society of Anesthesiologists (ASA) score (I/II vs. III/IV), body mass index (BMI), urinary diversion type (ileal conduit vs. neobladder vs. continent cutaneous), previous pelvic radiation therapy, neoadjuvant chemotherapy, and intraoperative blood transfusion. Linear regression was used to assess differences in LOS. Logistic regression was used for the return of bowel function, rate of any complications, and rate of complications grade 3. Patients were considered to have return of bowel function if they were able to tolerate oral intake after having their diet stopped because of symptoms. Additionally, total opioid use for the first 3 post-operative days was obtained from nurse recorded patient records. In order to standardize narcotic use, all opioids were converted to morphine equivalents using a publically available opioid analgesic converter (<http://www.globalrph.com/narcotic.cgi>) and then compared the values between the two groups. Post-operative pain scores for days 1 through 3 were recorded from standardized 0-10 (10 being extreme pain) pain scale responses taken by the covering nurse from the patient every 4 hours routinely. The average (mean) score from each post-operative day was compared between the two pain management modalities.

Due to the low serious complication rate, our logistic regression model was adjusted for variables that we felt would affect outcomes the most these included age, BMI, and ASA score (I/II vs. III/IV), in order to prevent over fitting. Bootstrap re-sampling was used to calculate 95% confidence intervals for adjusted differences in proportions.

As a sensitivity analysis to assess the few patients receiving the opposite pain management type during the time periods described above we repeated the above analyses excluding patients who did not receive PCEA or IV PCA during the appropriate time periods due to a contraindication. Finally, we created statistical process control charts (XmR chart for LOS and P-chart for grade 3 or higher complications), analyzed at quarterly intervals in order to enrich aggregate data and identify effects of interventions that are not easily recognized in cross-sectional data.

All statistical analyses were performed using Stata 12.0 (StataCorp, College Station, TX, USA).

Results

Of the 308 patients included for analysis, 97 (31%) received PCEA and 211 (69%) received IV PCA. Appendix 1 demonstrates temporal relationship to analgesic type. Table 1 shows baseline characteristics of each cohort. The cohorts were similarly matched in age, BMI, sex, ASA score, a preoperative diagnosis of diabetes, and final pathologic stage after RC.

The crude and adjusted differences in quality metrics are listed in Table 2. For our primary outcome metric of LOS, we identified no appreciable differences as a function of analgesic type. Given the non-normal distribution of LOS, we performed an additional analysis with log-transformed data that was also non-significant. Additionally, there were no statistical differences in bowel function return, complicate rates, and fluid bolus requirements.

Median total opioid use in the first three post-operative days was significantly higher in the IV PCA cohort (85mg, range 36-290) as compared to the PCEA group (45mg, range 13-80) ($p=0.0001$). Analgesic efficacy was significantly improved in patients who received PCEA on post-operative day 1 ($p=0.0001$) and 2 ($p=0.004$), however there was a slight trend towards improvement but was not statistically significant on post-operative day 3 ($p=0.77$). (Figure 1) Patients who received PCEA had similar median LOS (8 days IQR 6, 11 vs. 7 days IQR 6,10, $p=0.2$) and delayed return of bowel function (35% vs 33%) after RC when compared to patients who had IV PCA. (Table 2)

A sensitivity analysis was performed excluding the 11 patients who did not receive PCEA or IV PCA during the appropriate time periods due to a contraindication, however the results remained unchanged. Finally, in order to investigate temporal trends within aggregate data, we created statistical process control charts (Figure 2a-b). When analyzed by time interval for LOS and grade 3 or higher complications, no special cause signals were identified.

Discussion

We report our findings on two series of patients whose postoperative pain was managed by either PCEA or IV PCA following RC. Analgesic type was not associated with differences in LOS, time to return of bowel function, or overall complication rates. As defined by pain scores, analgesia was significantly improved in the PCEA cohort on post-operative days 1 and 2. In concordance with previous reports [7-10], median total opioid requirement was significantly less in the epidural cohort for the first three post-operative days, further substantiating our analysis.

RC with urinary diversion is a major abdominal procedure that can lead to complications and delayed recovery resulting in longer LOS. As such we found an overall median LOS of 7 days, largely due to either postoperative delay in return of bowel function or other complications. In a previous study, we reported a 9-day median LOS and a 67% overall complication rate, 29% of which was related to gastrointestinal complication following RC and urinary diversion [17].

Postoperative pain management is an important aspect of surgical convalescence impacting such factors as bowel function, early mobilization, and patient psyche. Additionally, delay in recovery of any of these factors can exacerbate complications of other organ systems and prolong hospital length of stay. In accordance with the findings demonstrated in this study, several randomized trials have shown improvement in early postoperative pain control with epidural use after pelvic surgery including radical prostatectomy and abdominal surgery for gynecological disorders [12-18]. It has been proposed that epidural use may hold further benefits to patient recovery than just improving patient comfort. These suggested benefits

include reductions in cardiovascular complications, venous thromboembolic events, and postoperative infections, as well as improved pulmonary recovery and return of bowel function [19]. However, a number of randomized studies have attempted to look further into these proposed benefits and have shown no improvements in return of bowel function or in pulmonary complications [10, 20, 21]. Our findings support this literature and additionally challenge the notion that hospital length of stay is positively impacted by regional anesthesia. We have shown that patients may have improved pain control with PCEA after RC, but other factors may play a more significant role in postoperative complications and patient recovery.

Several trials have previously been performed with a standardized postoperative pathway that used thoracic epidural anesthesia to assist patient recovery. They were able to show an improvement in time to recovery of bowel function, but this did not translate to improvement in LOS [9, 22]. In our study, a standardized postoperative pathway that was designed for a 7-day LOS was followed for both the PCEA and IV PCA cohorts. Patients were strictly held to the guidelines of this pathway unless an event occurred that required further patient care. No difference was found, by pain management type, in the proportion of patients who experienced a delayed return of bowel function (35% vs 33%; $p=0.6$), with a similar median LOS (8 vs 7 days; $p=0.2$) for both cohorts. However, neither of these differences reached statistical significance in our model. Similar findings were seen in the only other study comparing differences between PCEA and IV PCA for pain management after RC. The investigators of this study also found no difference in time to patient mobilization, time to eating of solid food, and LOS [15].

While we did not observe any significant differences between the two pain management strategies aside from overall opioid requirement and post-operative pain scores on POD 1 and 2, the confidence intervals for differences between IV PCA and PCEA in LOS, delayed return of bowel function, fluid bolus, and postoperative complication are too wide to exclude the possibility that pain management type plays an important role.

There are several important limitations to our study. The major limitation is that the patients were not randomized, making unmeasured confounders a distinct possibility. Since our data represent a time series analysis, 'learning' represents another possible threat to validity. The surgeon's differing experience levels by time period could have impacted on the various outcomes. Thus, our data represent the complex interaction of one surgeon, one clinical pathway, one approach to using epidural analgesia, and a unique health system. In particular, because we did not have a specific institutional approach to defining and replacing sub-optimal epidural anesthetics, it is possible that other institutions may experience different results with respect to the beneficial effects of opioid sparing analgesic techniques.

In conclusion, in our time series analysis, we were unable to detect an association of our approach to epidural analgesia with meaningful differences in LOS, time to return of bowel function, and complication rates. Our data represent a unique care process at one institution, and data should be thus be interpreted with caution when deciding on individualized patient care at other institutions.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Abbreviations

PCEA	patient-controlled epidural analgesia
IV PCA	intravenous patient-controlled analgesia
ASA	American Society of Anesthesiologists
LOS	length of stay
RC	radical cystectomy
EBL	estimated blood loss
BMI	body mass index

Figure 1. Mean pain scores compared between patients who received PCEA and IV PCA on POD#1-3

* Statistically significant unpaired t-test, p-value <0.05 for mean pain scores

Figure 2a **Figure 2b**

Figure 2. Statistical process control charts assessing temporal trends based on specific variables
A. XmR chart for hospital length of stay - Light grey lines represent upper and lower control limits based on 3-sigmas; vertical dashed line represents time point at which PCEA

use was routinely initiated; each year was subdivided into quarters represented by individual dots (Q1-4).

B. P-chart for proportion of patients experiencing grade 3 or higher complications (%)

- Light grey lines represent upper and lower control limits based on 3-sigmas; vertical dashed line represents time point at which PCEA use was routinely initiated; each year was subdivided into quarters represented by individual dots (Q1-4).

Table 1
Patient characteristics by pain management type

	PCEA (N=97)	IV PCA (N=211)	p-value
Age at surgery (years)	65 (59, 73)	68 (60, 74)	0.3
Days on pain management	5 (4, 6)	5 (4, 6)	0.2
Body mass index	28 (26, 30)	28 (25, 31)	0.8
Female	16 (16%)	34 (16%)	0.9
Diabetes	12 (12%)	30 (14%)	0.7
ASA Score			
1	0 (0%)	2 (1%)	0.2
2	23 (24%)	72 (34%)	
3	73 (75%)	134 (64%)	
4	1 (1%)	3 (1%)	
Stage at radical cystectomy			
pT0	26 (27%)	43 (20%)	0.8
pTa	4 (4%)	5 (2%)	
pT1	14 (14%)	27 (13%)	
pT2	12 (12%)	31 (15%)	
pT3	23 (24%)	62 (29%)	
pT4	1 (1%)	4 (2%)	
pTis	16 (16%)	37 (18%)	
Unknown	1 (1%)	2 (1%)	
Neoadjuvant chemotherapy	34 (35%)	79 (37%)	0.7
Previous radiation therapy	12 (12%)	12 (6%)	0.042
Blood transfusion	14 (14%)	65 (31%)	0.002
Estimated blood loss (cc)	550 (400, 800)	600 (450, 1000)	0.033
Operating room time (min)	294 (245, 339)	280 (217, 330)	0.15
Urinary diversion			
Continent cutaneous	2 (2%)	18 (9%)	0.003
Ileal conduit	37 (38%)	107 (51%)	
Neobladder	58 (60%)	86 (41%)	
Median total morphine equivalent use for POD1-3 (mg)	45 (13, 80)	85 (36-290)	0.0001
Mean Pain Score			
POD 1	3.2	4.38	0.0001
POD 2	2.53	2.99	0.004
POD 3	1.92	1.96	0.77

* Values presented are medians (interquartile range) for continuous variables (except for pain scores which are means) and frequency (%) for categorical variables. P-values are from the rank-sum test for continuous variables, unpaired t-test for pain scores and chi-square test for categorical variables.

Table 2
Multivariate analysis of postoperative features by pain management type

	Statistic	PCEA ¹ (N=97)	IV PCA ¹ (N=211)	Adjusted Difference (95% Confidence Interval) ²	p
Length of stay (days)	Mean (SD)	9.7 (6.9)	9.6 (5.3)	0.9 (-0.6, 2.4)	0.2
Delayed return of bowel function	N (%)	34 (35%)	69 (33%)	3.4% (-8.7%, 16.7%)	0.6
Fluid bolus within 3 postoperative days	N (%)	40 (41%)	84 (40%)	8.0% (-5.1%, 21.6%)	0.2
Complications within 90 days of surgery					
Overall complications	N (%)	55 (57%)	109 (52%)	2.7% (-11.0%, 16.7%)	0.7
Grade 3 [†]	N (%)	13 (13%)	25 (12%)	0.8% (-6.9%, 9.2%)	0.8

¹ Values presented are mean (standard deviation) for LOS and frequency (percent) for all other outcomes. The statistics are unadjusted means and proportions

² The differences between groups is the mean/rate in the PCEA group minus the IV PCA group. Differences have been adjusted in multivariable regression models that has been adjusted for age, operating time, estimated blood loss (EBL), American Society of Anesthesiologists (ASA) score (I/II vs. III/IV), body mass index (BMI), urinary diversion type (ileal conduit vs. continent cutaneous), previous pelvic radiation therapy, neoadjuvant chemotherapy, and intraoperative blood transfusion. Due to a limited number of patients who experienced a grade 3 complication, the logistic regression model for grade 3 complications was adjusted for estimated blood loss, receipt of packed red blood cell, and neoadjuvant radiation therapy only.