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Ketorolac Use and Incidence of Postoperative Bleeding in an ERAS Colorectal Surgical Population: A Quality Analysis of Practice

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Background Ketorolac is an effective analgesic adjunct and is currently used in Enhanced Recovery After Surgery (ERAS) protocols. However, investigation into its safety profile is warranted in specific surgical populations. This Quality Improvement (QI) study sought to examine the association of ketorolac to increased postoperative bleeding risk, increased postoperative renal impairment, and 30-day readmission within an ERAS protocol for colorectal surgery.

Methods A retrospective review was conducted of 158 patients enrolled in an existing ERAS protocol for colorectal surgery with at least one dose of ketorolac administered in the perioperative period. Outcomes of postoperative bleeding, 30-day readmission, and preoperative/postoperative serum creatinine levels were assessed.

Results There was no statistically significant difference in the incidence of postoperative bleeding compared to a known population. There was a significant association of 30-day readmissions with documented evidence of bleeding ($P = 0.037$). There was no significant change in the preoperative and postoperative serum creatinine. Multivariate logistic regression analysis found no association of postoperative bleeding with pre-existing chronic non-steroidal anti-inflammatory drug (NSAID) use or preoperative serum creatinine.

Conclusions Ketorolac is not associated with an increased risk of postoperative bleeding in colorectal ERAS surgical patients. However, postoperative bleeding does predict the likelihood for 30-day readmissions.

Keywords

ketorolac, colorectal surgery, postoperative bleeding

Disciplines

Digestive System Diseases | Nursing | Surgery

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Introduction

Ketorolac, a nonselective cyclooxygenase (COX) inhibitor, is a potent analgesic frequently used in the operating room and the inpatient setting [1, 2]. In a range of surgical populations, the use of ketorolac has proven successful as a multimodal approach to postoperative pain management [2, 3]. However, its use in the perioperative setting is controversial given concerns over ketorolac's effect on bleeding related to platelet dysfunction [4, 5]. Conflicts in reported data have created contrariety among perioperative providers with regard to ketorolac administration and the postoperative risks for surgical patients [4-6].

A comprehensive review of the literature concluded that in the perioperative setting, ketorolac use does not cause an increased risk of bleeding in a multitude of surgical procedures and patient populations [6-12]. As an effective nonopioid analgesic for mild to moderate postoperative pain, ketorolac use warrants additional investigation to assess its safety profile in various surgical specialties and patient populations, including colorectal surgery.

The inclusion of ketorolac in Enhanced Recovery After Surgery (ERAS) protocols acknowledges its safety and efficacy among select surgical specialties. Ketorolac has been proven to both provide postoperative analgesia and have an opioid-sparing effect, thus decreasing post-surgical opioid consumption [3]. Numerous studies have evaluated the risk and incidence of non-steroidal anti-inflammatory drug (NSAID)-induced postoperative bleeding after surgery, but the majority of findings were inconclusive, including a meta-analysis of 27 randomized controlled trials [6]. Many providers continue to be hesitant to choose an NSAID as a postoperative analgesic due to the uncertainty of the risk profile for bleeding. A retrospective health record review was conducted with ERAS protocol surgical patients in the colorectal

department of a large academic medical center to evaluate the incidence of postoperative bleeding complications.

Material and Methods

This retrospective quality improvement project sought to determine if ketorolac use in an ERAS-protocol colorectal surgical population is associated with increased postoperative bleeding, increased rate of 30-day readmission, or a postoperative increase in serum creatinine levels. This project was deemed exempt from the Institutional Review Board as a Quality Improvement (QI) study. Utilizing the Lean methodology framework, a retrospective chart review was conducted in an existing database of ERAS colorectal surgical patients at a single academic medical center [13]. Investigators conformed to SQUIRE guidelines to ensure transparency of reporting [14].

Sample and Setting

Patient data were accessed through a database maintained by author, SS, and the electronic medical record (EMR). Participants included in the study had undergone elective colorectal surgeries performed between January 2015 and July 2017 and were all enrolled in an ERAS protocol. As part of the protocol, patients received at least one dose of intravenous (IV) ketorolac in the perioperative period, and the majority continued this therapy for up to 48 hours postoperatively. Those who had not undergone an elective colorectal surgical procedure or had no exposure to IV ketorolac were excluded from analysis (Figure 1).

Study Variables

Variables collected from the EMR included age, sex, race, American Society of Anesthesiologists (ASA) physical status, primary preoperative diagnosis, procedure type, length of postoperative hospital stay, presence or absence of 30-day readmission, preoperative chronic NSAID use, ketorolac dose (mg), preoperative serum creatinine level (mg/dL), day-one postoperative serum creatinine level (mg/dL), postoperative blood transfusion, postoperative endoscopic intervention and/or documented evidence of postoperative bleeding. The primary study outcome, postoperative bleeding, was defined as any documented sign of bleeding during the hospital length of stay, including the need for blood transfusion or endoscopic evaluation of suspected bleeding. The secondary outcome of 30-day readmission was evaluated by examining the incidence of readmission among all included patients. An additional outcome of renal dysfunction was evaluated by comparison of preoperative and day-one postoperative serum creatinine level. Testing for interrater reliability for data collection was negated by the use of two researchers simultaneously reviewing records, extracting data, entering data into an electronic database and verifying the accuracy of data entry. Discrepancies in interpretation of data were resolved with decision rules and discussion by both researchers until agreement was reached.

Statistical Analysis

Descriptive statistics (e.g. means, standard deviations, medians and frequencies) were used to report sample characteristics. Bivariate statistics evaluated associations between each outcome of interest. A one-sample chi-square test was performed to evaluate bleeding risk, comparing the study sample to a known incidence of postoperative bleeding among colorectal surgical patients derived from a meta-analysis of colorectal surgical complication rates [15]. The Wilcoxon-Signed ranks test compared medians between pre- and postoperative serum creatinine levels.

Mann-Whitney U tests compared medians for several variables between patients with and without documented evidence of bleeding and 30-day readmissions. A multivariate logistic regression model was constructed for bleeding and 30-day readmission to estimate the odds ratio of the risk of bleeding. Variables were stratified to examine the influence on primary and secondary outcomes. An $\alpha < 0.05$ was set and study subjects with missing data for secondary outcomes were not included in the calculations. The overall fit of models was evaluated using Akaike Information Criteria (AIC) and a Hosmer-Lemeshow test for goodness of fit with $p > 0.05$ indicating that the fitted predicted probabilities did not deviate from the observed probabilities of the data. Statistical analysis was performed using SPSS Version 24.0 (IBM Corp, 2016, Armonk NY) and R 3.5.1 (R Foundation, 2018, Vienna, Austria).

Results

A total of 242 patient charts were included in the ERAS database and 158 patients were selected based upon meeting all inclusion criteria (Figure 1). The database included patients who had multiple ERAS-protocol procedures on separate dates. If the separate entries for a single patient met inclusion criteria, these results were included in final analyses. Participants included were aged 18-89 years, 49.4% female, 50.6% male, with a mean age of 50.4 years (Table 1). Demographic information for race included 73.4% white, 23.4% black and 3.2% other. Of the underlying etiologies, 27.2% of patients had a preoperative diagnosis of cancer, 40.5% of inflammatory bowel disease, 19.6% of diverticulitis, and 12.7% trauma or other diagnoses. Doses of ketorolac were either 15 milligrams of IV ketorolac (20.3% of cases) or 30 milligrams of IV ketorolac (79.7% of cases). A total of 8.8% of patients had a hospital readmission for all-causes within 30 days of discharge (Table 2). Of the patients who had a 30-day readmission, 4

(28.6%) had evidence of bleeding upon readmission or at some time during the primary hospitalization. Twelve patients (7.6%) had documented evidence of postoperative bleeding (Table 2). When compared to a known incidence of postoperative bleeding in colorectal surgical patients (7.6%), a Pearson chi-square analysis indicated no statistically significant difference between our sample data and a known comparator [$\chi 2(1, n=158) < 0.001$, $p = 0.999$] [14]. Examining the primary and secondary outcomes of interest as they relate to sample characteristics, there was a significant influence on postoperative bleeding risk from those who had a diagnosis of diverticulitis ($p = 0.005$) (Table 2). A significant difference ($p = 0.013$) existed between the proportion of patients who had evidence of bleeding and had subsequent readmission versus those who had no signs of postoperative bleeding. As it relates to 30-day readmission, a Fisher's exact test of proportions indicated a significant difference in the proportion of patients requiring a transfusion ($p = 0.004$) or endoscopic intervention ($p = 0.007$) who also had evidence of postoperative bleeding and were readmitted within 30-days versus those with no evidence of postoperative bleeding (Table 2). Bivariate statistics utilizing a Mann-Whitney U test showed a significant difference in the median length of stay between the patients who had signs of bleeding and those who did not (4 days vs. 3 days, respectively, $p = 0.008$) (Table 2). There was no significant influence of gender, race, ASA status, type of procedure, or chronic NSAID use on the primary and secondary outcomes of interest (Tables 2, 3, 4).

Risk of Bleeding

Compared to those with preoperative diagnosis of diverticulitis, individuals with cancer were 93% less likely to have postoperative bleeding [Adjusted Odds Ratio (AOR) = 0.068; 95% CI = 0.003, 0.484; $p = 0.022$] (Table 3).

Odds of 30-Day Readmission

A multivariate approach identified that individuals who were readmitted within 30 days had a 6 times greater odds of having had evidence of postoperative bleeding compared to those patients who were not readmitted (AOR = 6.163; 95% CI = 1.150, 32.186; $p = 0.028$) (Table 3). Further, patients who had evidence of postoperative bleeding had a 5 times greater risk of 30-day readmission (AOR = 5.436; 95% CI = 1.221, 21.646; $p = 0.018$) (Table 4). The influence of preoperative chronic NSAID use and hospital length of stay were insignificant related to 30-day readmission (Table 4).

Serum Creatinine Levels

There was no statistically significant change in postoperative creatinine levels for patients who received any dose of intraoperative IV ketorolac ($z = -7.1$, $p = 0.667$).

Discussion

Bleeding

This study is among few to evaluate the incidence of postoperative bleeding in a sample of colorectal surgical patients receiving ketorolac as part of an ERAS protocol. Findings from this retrospective review found no difference in our sample's bleeding complication rate when compared to a population of colorectal surgical patients [15]. This suggests that there may be no increased risk of bleeding associated with ketorolac use in the colorectal surgical population. Other studies have also corroborated that perioperative administration of ketorolac poses no increased risk for bleeding with many types of surgeries [6-12]. Notably, a 2011 meta-analysis of

27 randomized controlled trials found no significant increase in postoperative bleeding in patients who received ketorolac when compared to control groups [6].

Having a complication of bleeding did contribute to a statistically significant longer median for length of postoperative hospital stay, 4 days for patients with postoperative bleeding, and 3 days for patients without. Shorter length of hospital stay is associated with lower costs when compared to patients with longer stay, and earlier discharge has been linked with lower 30-day readmission rates [16, 17]. Overall, surgical complications increase length of hospital stay [18], and studies have shown significantly shorter length of stay between ERAS and non ERAS patients by 2.6 days [19]. Our data suggests that within this sample of ERAS-protocol colorectal surgical patients, postoperative bleeding increases length of hospitalization by 1 day.

Compared to those with cancer diagnoses, individuals with diverticulitis as an indication for colorectal surgery have a 15 times greater odds of postoperative bleeding. This finding is in contrast with current data suggesting no difference between major complication rates based on surgical indication [19, 20]. One study found malignant neoplasm to be the surgical indication associated with higher complication rates [21]. However, both aspirin and NSAID use has been linked to increased lower gastrointestinal bleeding in patients with diverticular disease [22, 23]. Because our sample contained a small proportion of patients with diverticulitis, our finding must be cautiously interpreted but underscores the need to further investigate the association between diverticular disease and postoperative bleeding.

There was no association between preoperative chronic NSAID use and postoperative bleeding. However, a 2011 meta-analysis linked chronic aspirin and NSAID therapies with increased risk of lower gastrointestinal bleeding in non-surgical patients with diverticulitis [23]. Our sample - in which 100% of patients received perioperative ketorolac - showed no deviation

of postoperative bleeding risk from the known comparator, in addition to no increased risk with chronic aspirin or NSAID therapy [15].

30-Day Readmission

This study demonstrated that patients with evidence of postoperative bleeding were 7 times more likely to be readmitted within 30 days of postoperative discharge. If patients received a blood transfusion, this risk was 11 times greater. Readmission rates within 30 days of discharge are important metrics for hospitals and healthcare providers due to reduced financial reimbursement for the subsequent hospitalization. This reduction in payment to hospitals from the Centers for Medicare & Medicaid Services (CMS) for potentially preventable hospitalizations is estimated to reduce spending by approximately $500 million in 2019 [24]. In addition, this regulation in reimbursement holds hospitals accountable to reduce re-hospitalization. Our results add to the evidence showing that higher complication rates are associated with increased readmissions, regardless of ERAS or non-ERAS protocol [18, 19].

Serum Creatinine

Aside from bleeding risk, a concern when using NSAIDs in the perioperative setting is the risk of renal impairment. The analysis showed no statistically significant change in postoperative creatinine levels for patients who received any dose of intraoperative IV ketorolac. This finding is supported by a 2007 Cochrane review that included 23 trials and concluded that NSAID administration reduces creatinine clearance by 16 mL/min on postoperative day 1 and causes no change in serum creatinine levels compared to placebo administration in patients with normal renal function [25]. This decrease in creatinine clearance was deemed as clinically insignificant

and does not risk renal failure. Similarly, our findings apply to patients with normal baseline renal function, as patients with preoperative renal disease were excluded from the full ERAS protocol and did not receive ketorolac. Perioperative ketorolac has an acceptable safety profile when administered to those with normal renal function.

Limitations

While our study included all eligible patients enrolled in an ERAS protocol, the sample size was relatively small. This may have affected inferences drawn from the results and contributed to wide confidence intervals around mean values. Limited sample sizes may be less representative of broader samples and hamper the ability to generalize findings to a larger population. However, data generated from this exploratory project support the need for future prospective investigations of ketorolac with colorectal surgical populations.

With any observational study, there is always potential for bias in the results due to unobserved or unaccounted-for mediator/moderator of the outcome of interest. To reduce this bias, our sample was all-inclusive of eligible patients, and data were collected using two researchers who simultaneously extracted and verified all data. The sample for this project was relatively homogenous with each patient receiving standard care directed by an ERAS protocol. This reduced practice variations in the management of patients that may have introduced potential confounding variables influencing outcomes with ketorolac. The lack of a control group is also a limitation that would have allowed a comparison of bleeding complications in those having colorectal surgery but not receiving ketorolac.

Conclusion

In conclusion, ketorolac is not associated with an increased risk of postoperative bleeding in colorectal ERAS surgical patients. Ketorolac is further not associated with a decrease in postoperative renal function as evidenced by a change in serum creatinine levels. An association does exist between postoperative bleeding and increased 30-day readmission rates, as well as increased length of stay.

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Table 1: Sample Characteristics (n = 158)

	Mean (SD)	
Age (years)	50.4 (16.9)	
Pre Creatinine (mg/dL)	0.85 (0.2)	
POD 1 Creatinine (mg/dL)	0.87 (0.2)	
Length of Stay (days)	3.3 (1.8)	
	N	**%**
Gender		
Female	78	49.4%
Male	80	50.6%
Race		
Black	37	23.4%
White	116	73.4%
Other	5	3.2%
ASA Classification		
1	3	1.9%
2	104	65.8%
3	51	32.3%
Diagnosis		
Cancer	43	27.2%
IBD	64	40.5%
Diverticulitis	31	19.6%
Trauma/Other	20	12.7%
Procedure		
Laparoscopic colectomy	99	62.7%
Exploratory laparotomy	23	14.6%
Closure enterostomy	22	13.9%
Other	14	8.9%
Ketorolac Dose		
30 mg	126	79.7%
15 mg	32	20.3%
30-day Readmission		
No	144	91.1%
Yes	14	8.9%
Transfusion		
No	149	94.3%
Yes	9	5.7%
Endoscopic Intervention		
No	156	98.7%
Yes	2	1.3%
Evidence of Bleeding		
No	146	92.4%
Yes	12	7.6%
Preoperative NSAID use		
No	122	77.2%
Yes	36	22.8%

POD 1 = post-operative day 1; ASA = American Society of Anesthesiologists; IBD = inflammatory bowel disease

Table 2: Comparison of Outcomes Based on Sample Characteristics*

	Evidence of Postoperative Bleeding			**30-day Readmission**		
	No	**Yes**		**No**	**Yes**	
	Median	Median	P-value	Median	Median	P-value
Age	50.50	59.50	0.217	50.51	52.50	0.801
Pre Creatinine	0.84	0.77	0.070	0.84	0.90	0.476
POD 1 Creatinine	0.84	0.79	0.293	0.83	0.89	0.383
Ketorolac Dose	30	30	0.242	30	40	0.912
Length of Stay	3.0	4.0	*0.008*	3	3.5	0.138
	N	N	P	N	N	P
Gender			0.999			0.160
Female	72	6		74	4	
Male	74	6		70	10	
Race			0.528			0.411
Black	36	1		35	2	
White	105	11		105	11	
Other	5			4	1	
ASA			0.198			0.355
1	3	0		3	0	
2	93	11		92	12	
3	50	1		49	2	
Diagnosis			*0.005*			0.779
Cancer	42	1		40	3	
IBD	62	2		59	5	
Diverticulitis	24	7		27	4	
Trauma/Other	18	2		18	2	
Procedure			0.641			0.404
Laparoscopic colectomy	92	7		92	7	
Exploratory laparotomy	22	1		21	2	
Closure enterostomy	20	2		18	4	
Other	12	2		13	1	
Readmission			*0.013*			
No	136	8				
Yes	10	4				
Transfusion			*0.000*			*0.004*
No	142	7		139	10	
Yes	4	5		5	4	
Endoscopic			0.147			*0.007*
No	145	11		144	12	
Yes	1	1		0	2	
NSAID			0.3			0.738
No	111	11		110	12	
Yes	35	1		34	2	

* Measures of association between continuous variables and the dichotomous outcomes assessed using Mann Whitney U test and Fisher's Exact for categorical variables.

POD 1 = post-operative day 1; ASA = American Society of Anesthesiologists; IBD = inflammatory bowel disease; NSAID = non-steroidal anti-inflammatory drug

Table 3: Primary Outcome: Odds of Bleeding

	[t]AIC= 80.9			
	OR	**LCI**	**UCI**	**P**
Intercept	0.036	0.002	0.519	0.021
Age	1.038	0.986	1.096	0.162
Preop NSAID Use	0.272	0.013	1.857	0.258
30-day Readmission	6.163	1.150	32.186	*0.028*
Diagnosis				
Cancer	0.068	0.003	0.484	*0.022*
Trauma/Other	0.419	0.052	2.295	0.348
Diverticulitis	Ref			
IBD	0.173	0.022	0.915	0.054
Gender				
Female	Ref			
Male	0.890	0.192	4.005	0.878

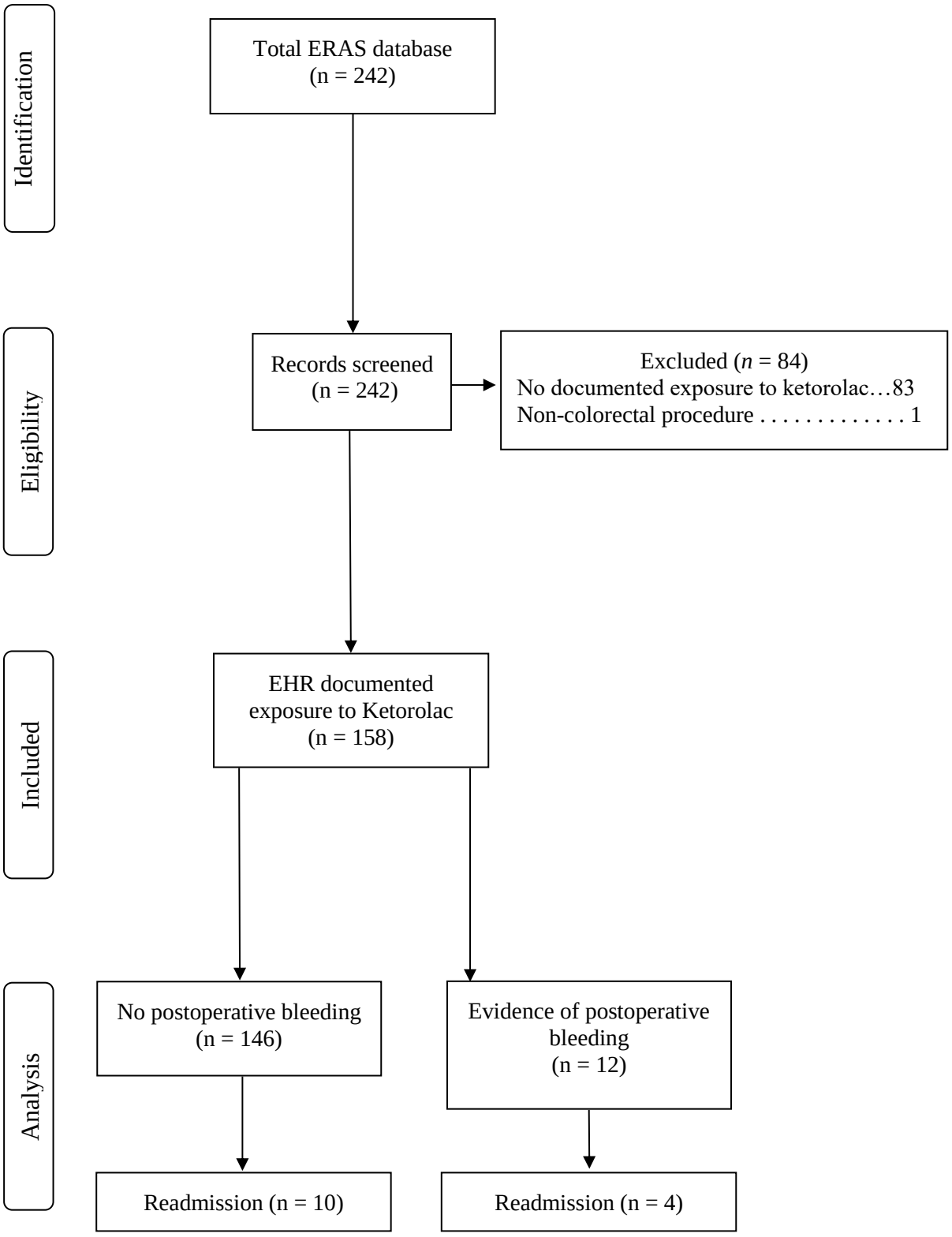
[t] = Akaike information criterion (AIC)
OR = Odds ratio; LCI = Lower confidence interval; UCI = upper confidence interval
IBD = inflammatory bowel disease; NSAID = non-steroidal anti-inflammatory drug

Table 4: Secondary Outcome: Odds of Readmission

	[t]AIC= 94.4			
	OR	**LCI**	**UCI**	**P**
Intercept	0.046	0.013	0.141	0.000
Postop Bleeding	5.436	1.221	21.646	*0.018*
Preop NSAID Use	0.576	0.083	2.425	0.500
Length of Stay	1.186	0.889	1.517	0.193

[t] = Akaike information criterion (AIC)
OR = Odds ratio; LCI = Lower confidence interval; UCI = upper confidence interval
NSAID = non-steroidal anti-inflammatory drug

Figure 1



Flow Diagram: Patient Selection Process for Quality Improvement.