ORIGINAL CONTRIBUTIONS





Bariatric Surgery in Patients on Chronic Anticoagulation Therapy

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Abstract

Background Perioperative management of chronically anti-coagulated patients undergoing bariatric surgery requires a balance of managing hemorrhagic and thromboembolic risks. The aim of this study is to evaluate the incidence of hemorrhagic complications and their management in chronically anticoagulated (CAT) patients undergoing bariatric surgery.

Methods A retrospective review of CAT patients undergoing bariatric surgery at an academic center from 2008 to 2015 was studied. **Results** A total of 153 patients on CAT underwent surgery [Roux-en-Y gastric bypass (n = 79), sleeve gastrectomy (n = 63), and adjustable gastric banding (n = 11)] during the study period: 85 patients (55%) were females; median age was 56 years (interquartile range [IQR] 49–64), and median BMI was 49 kg/m² (IQR 43–56). The most common indications for CAT were venous thromboembolism (n = 87) and atrial fibrillation (n = 83). Median duration of procedure and estimated intraoperative blood loss was 150 min (IQR 118–177) and 50 ml (IQR 25–75), respectively. Thirty-day postoperative complications were reported in 33 patients (21.6%) including postoperative bleeding (n = 19), anastomotic leak (n = 3), and pulmonary embolism (n = 1). Nineteen patients (12%) with early postoperative bleeding were further categorized to intra-abdominal (n = 10), intraluminal (n = 6), and at the port site or abdominal wall (n = 3). All-cause readmissions within 30 days of surgery occurred in 19 patients (12%). There was no 30-day mortality.

Conclusion In our experience, patients who require chronic anticoagulation medication are higher than average risk for postoperative complications and all-cause readmission rates. Careful surgical technique and close attention to postoperative anticoagulation protocols are essential to decrease perioperative risk in this high-risk cohort.

Keywords Bariatric surgery · Anticoagulation · Postoperative bleeding · Roux-en-Y gastric bypass · Sleeve gastrectomy · Readmissions

Introduction

Perioperative management of patients with obesity requiring chronic anticoagulation therapy (CAT) is challenging, with

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Suriya Punchai suriya149@gmail.com respect to maintaining a fine balance between the increased risks of thromboembolic versus hemorrhagic complications [1]. CAT is a known risk factor for postoperative bleeding and thromboembolic events in patients undergoing elective

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surgical procedures [2–5]. Thus, perioperative management of this high-risk group should be tailored to patient characteristics and clinical setting including comorbidities, indication for the CAT, elective vs. emergent procedure being performed, need for perioperative bridging and therapeutic timing of the anticoagulants, risk of venous thromboembolism (VTE) and hemorrhage, and consequences of bleeding and the available expertise to control postoperative bleeding.

In one of the meta-analyses on the early postoperative outcomes of chronically anticoagulated patients with periprocedural bridging, the overall risk of VTE and major bleeding was 1 and 4.2%, respectively [6]. Increasingly, a large number of obese patients requiring CAT are opting for bariatric surgery [7]. CAT patients undergoing bariatric surgery may experience impaired absorption of anticoagulation medications postoperatively. Contributory factors include alteration in the anatomy of gastrointestinal tract, weight loss, and lack of oral intake. This may eventually result in difficult achievement of therapeutic levels postoperatively [8–10].

Current literature on early postoperative outcomes of patients on CAT undergoing bariatric surgery is limited to small retrospective series, with variable results on postoperative hemorrhagic events [1, 7, 10–12]. This study aims to evaluate the incidence of early postoperative morbidity in chronically anti-coagulated patients undergoing primary laparoscopic bariatric surgery at our institution. The primary end point of the study was defined as incidence of early postoperative (\leq 30 day) hemorrhagic and thromboembolic complications in patients on CAT. Secondary endpoints included reoperations, readmissions, major, and minor complications.

Materials and Methods

Study Cohort

After approval by our Institutional Review Board, a retrospective review of a prospectively maintained database was completed to identify patients with CAT that had undergone bariatric surgery from February 2008 to August 2015 at our institution. All patients with CAT who had undergone primary laparoscopic bariatric procedures including Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and adjustable gastric banding (AGB) were included. Patients without CAT and those in whom no data was available were excluded.

Definition of Chronic Anticoagulation Therapy

CAT was arbitrarily defined as the use of oral anticoagulants for at least 1 month before the bariatric surgery. Treatment was monitored according to the International normalization ratio (INR) for the oral anticoagulants, and therapeutic range for these patients was in between 2 and 3 [13] according to their co-morbidities.

Perioperative Management of Anticoagulation Therapies

All patients underwent a preoperative consultation with bariatric physician and anesthesiologist, during which perioperative management of anticoagulation was planned. Indications for bridging anticoagulation therapies included the following: mechanical heart valve, venous thromboembolism (VTE) (recent, recurrent, or with thrombophilia), or high-risk conditions for stroke in patients with atrial fibrillation (CHA2DS2VASc score more than 5). For the bridging, CAT was stopped approximately 5 days before surgery and LMWH or UH was initiated 2 days after the last dose of CAT; the choice of one or the other was mainly based on the bariatric physician's recommendation. The last preoperative dose was administered 24 h before the surgery. Patients received perioperative pharmacoprophylaxis for VTE. Postoperative bridging was initiated on day 2 or day 3 after surgery, once the hemostasis was achieved until INR was therapeutic. After surgical procedure and upon discharge from the hospital, these patients are followed up by their primary care physicians or the INR clinic.

Data Collection and Statistical Analysis

Study data was collected and managed using REDCap (Research Electronic Data Capture) hosted at our institution and customized for this study [14]. Collected data included baseline patient demographics; charlson comorbidity index [15]; CHA₂DS₂VASc score (congestive heart failure, hypertension, age, diabetes mellitus, history of stroke or transient ischemic attack, vascular disease, and gender) [16]; weight-related comorbidities (diabetes mellitus, hypertension, hyperlipidemia, reflux disease, sleep apnea), indications for CAT (prior VTE, atrial fibrillation, mechanical/prosthetic heart valve, and thrombophillic conditions), and past history of abdominal procedures.

Furthermore, type of anticoagulant, the use of therapeutic and bridge anticoagulant, and its timing with respect to the bariatric procedure (preoperative, intraoperative, and postoperative) were collected. Perioperative variables included preoperative laboratory data (level of hemoglobin, platelet count, partial thromboplastin time, prothrombin time, and INR), American Society of Anesthesiologist (ASA) score, and concurrent procedures performed, duration, type (RYGB, SG, and AGB), and technique (laparoscopic, open, or laparoscopic converted to open). In addition, intraoperative complications (significant bleeding > 250 ml, need for intraoperative transfusions, and conversion to open surgery) and length of hospital stay were also noted.

Postoperative data constituted early postoperative complications (< 30 days). Postoperative complications were categorized as bleeding complications, major complications, and minor complications according to the ASMBS outcomes reporting standards [17]. Bleeding complications were further categorized depending on the source of bleeding (intra-abdominal, intraluminal, or port-site) and the management performed (need for reoperation and transfusion and stopping anticoagulation or conservative management). Major complications included venous thromboembolism requiring administration of anticoagulant/intervention, anastomotic leak requiring reoperation/percutaneous drainage/stent placement/ management with parenteral nutrition and nil per oral (NPO), bowel obstruction requiring reoperation, trocar site hernia requiring reoperation, myocardial infarction, renal failure requiring dialysis, respiratory failure requiring intubation, chronic nausea/vomiting requiring parenteral nutrition, surgical site infection requiring debridement/washout and small bowel stenosis, and stricture or obstruction requiring reoperation. Minor complications included poor oral intake requiring intravenous hydration/enteral access, marginal ulcer diagnosed on upper endoscopy, anastomotic stricture requiring dilation, pneumonia requiring antibiotics, port site seroma, anemia managed with transfusion, acute renal failure managed with intravenous hydration, postoperative ileus managed conservatively, trocar site infection managed with drainage and local wound care, urinary tract infection requiring antibiotics and negative re-exploration performed to rule out leak, or unexplained tachycardia. Continuous variables were summarized by medians with interquartile range (IQR) and categorical variables by counts and percentages.

Results

Demographics

There were 3882 patients who underwent primary laparoscopic bariatric surgery during the study period. We identified 153 patients (3.9%) on CAT among them. Eighty-five (56%) patients were female with median age of 56 years (IQR 49–64) and the median preoperative BMI of 49 kg/m² (IQR 43–56). Associated pertinent comorbidities included hypertension (n = 130, 85%), sleep apnea (n = 122, 80%), dyslipidemia (n = 107, 70%), diabetes mellitus (n = 90, 59%), gastroesophageal reflux disease (n = 66, 43%), chronic obstructive pulmonary disease (n = 15, 10%), and renal insufficiency (n = 15, 10%). Among the study cohort, 83 patients (54%) had a previous history of abdominal surgery.

Indications for chronic anticoagulation were VTE (n = 87), atrial fibrillation (n = 83), prosthetic heart valve (n = 4), coagulation disorder including factor V Leiden deficiency (n = 8), protein C deficiency (n = 6), protein S deficiency (n = 3), antiphospholipid syndrome (n = 2), and prothrombin gene mutation (n = 1). One hundred seventeen patients (76%) had a single indication for CAT while 36 patients (24%) had more than one indication for CAT. Median CHA₂DS₂VASc score was 4

(IQR 3–5). Eighty-five percent patients had a CHA_2DS_2VASc score \geq 3. The demographic data is summarized in Table 1.

Perioperative Details

Preoperative therapeutic anticoagulants included the following: warfarin (n = 128, 85%), LMWH (n = 5, 3%), dabigatran (n = 9, 5%), apixaban (1, 1%), and rivaroxaban (n = 10, 6%). Duration of discontinuation of therapeutic anticoagulation before index surgery was 5 days (IQR 5–6), and it was resumed a median of 2 days postoperatively (IQR 1–3). Postoperatively, two patients were not resumed on therapeutic anticoagulation as both the patients no longer required long-term oral anticoagulants. Bridging dose of anticoagulants was used in 74 patients (48%) with either LMWH (n = 50), UH (n = 14), LMWH and UH together (n = 5), or fondaparinux (n = 5). Most patients (94%) received perioperative pharmcothromboprophlaxis. Median preoperative hemoglobin and INR were 13.6 mg/dl

 Table 1
 Baseline characteristics

Demographics	<i>n</i> = 153
Age (years), median, IQR	56 (49–64)
Pre-operative BMI (kg/m ²), median, IQR	49 (43–56)
Females— $\%$ (<i>n</i>)	56 (85)
Charlson comorbidity index (age adjusted), median, IQR	3 (2–5)
CHA2DS2VASc score, median, IQR	4 (3–5)
Associated comorbidities— $\%$ (<i>n</i>)	
Diabetes mellitus	59 (90)
Hypertension	85 (130)
Dyslipidemia	70 (107)
Reflux disease	43 (66)
Sleep apnea	80 (122)
Myocardial infarction	16 (25)
Congestive heart failure	29 (44)
Chronic obstructive pulmonary disease	10 (15)
Renal insufficiency	10 (15)
Previous abdominal surgeries	54 (83)
Indications for anticoagulation— $\%$ (<i>n</i>)	
Venous thromboembolism	57 (87)
Atrial Fibrillation	54 (83)
Mechanical/Prosthetic heart valve	3 (4)
Thrombophillic Conditions	11 (17)
Factor V leiden mutation, n	8
Protein C deficiency, n	6
Protein S deficiency, n	3
Anti-phospholipid mutation, n	2
Prothrombin gene mutation, n	1

IQR inter-quartile range, *n* number of patients available, % percentage, kg/m^2 kilogram per meter square

Pertinent anticoagulant and laboratory data	<i>n</i> = 153	
Preoperative use of the rapeutic anticoagulants— $\%$ (<i>n</i>)		
Warfarin	85 (128)	
LMWH	3 (5)	
Dabigatran	5 (9)	
Apixaban	1 (1)	
Rivaroxaban	6 (10)	
Days from stopping anticoagulant medication to surgery, median, IQR	5 (5-6)	
Use of bridge anticoagulant— $\%$ (<i>n</i>)	48 (74)	
LMWH only, <i>n</i>	50	
UH only, <i>n</i>	14	
LMWH and UH, n	5	
Fondaparinux, N	5	
Use of prophylactic anticoagulant— $\%$ (<i>n</i>)	94 (144)	
Postoperatively resumed anticoagulants— $\%$ (<i>n</i>)		
Warfarin	83 (124)	
LMWH	4 (7)	
Dabigatran	6 (10)	
Apixaban	1 (1)	
Rivaroxaban	5 (9)	
Patients not resumed on therapeutic anticoagulants	1 (2)	
Days to resuming anticoagulant medication after surgery, median, IQR	2 (1–3)	
Preoperative laboratory data		
Hemoglobin, mg/dL, median, IQR	13.6 (12.4–14.5	
Platelet count, thousands/mm ³ , median, IQR	232 (195–286)	
Partial thromboplastin time, seconds, median, IQR	32.3 (29.9–34.9	
Prothrombin time, seconds, median, IQR	13.2 (12.1–16.3	
International normalized ratio, median (IQR)	1.2 (1.1–1.5)	

IQR inter-quartile range, *n* number of patients available, % percentage, mg/dL milligram per deciliter, mm^3 millimeter cubic, *LMWH* low-molecular weight heparin, *UH* unfractionated heparin

(IQR 12.4–14.5) and 1.2 (IQR 1.1–1.5), respectively. Data on perioperative use of anticoagulants is summarized in Table 2.

Bariatric procedures performed included RYGB (n = 79), SG (n = 63), and AGB (n = 11). Median duration of procedure and estimated intraoperative blood loss was 150 min (IQR 118–177) and 50 ml (IQR 25–75), respectively. Significant intraoperative bleeding or intraoperative transfusions were reported in six patients. The median postoperative length of stay was 4 days (IQR 3–5). Pertinent perioperative data is summarized in Table 3.

Thirty-Day Postoperative Details

Early postoperative complications (<30 days) were observed in 33 patients (21.6%) including postoperative bleeding (n =19), anastomotic leak (n = 3), pulmonary embolism (n = 1), organ space surgical site infection (n = 1), poor oral intake requiring intravenous (IV) hydration or enteral access (n =3), marginal ulcer (n = 3), anastomotic stricture (n = 1), pneumonia requiring antibiotics (n = 1), port site seroma (n = 1), anemia managed with transfusion (n = 1), and acute renal failure managed with IV hydration (n = 1). Overall 30-day composite complications in patients with single and multiple indications for CAT were 24% (n = 27/117) and 17% (n = 6/36), respectively.

Nineteen patients (12%) had early postoperative bleeding (< 30 days) were further categorized based on the site of bleeding as follows: intra-abdominal (n = 10), intraluminal (n = 6), and at the port site or abdominal wall (n = 3). Thirteen patients with postoperative bleeding were managed conservatively with transfusion of blood products, and six patients required surgical intervention and blood product transfusions. Four out of 19 patients developed bleeding complications as a result of supratherapeutic INR postoperatively. The incidence of bleeding complications was further categorized according to indications for CAT [single indication for CAT, 14% (16/117); multiple indications for CAT, 8% (3/36)], type of CAT [patients on warfarin, 14% (18/128) and patients

Table 3 Perioperative data

ASA class—% (n)	
Class 1	0 (0)
Class 2	3 (4)
Class 3	75 (115)
Class 4	22 (34)
Class 5	0 (0)
Laparoscopic bariatric procedure performed—% (n)	
Roux-en-Y gastric bypass	52 (79)
Sleeve gastrectomy	41 (63)
Adjustable gastric banding	7 (11)
Bariatric procedures with concurrent surgeries— $\%$ (<i>n</i>)	14 (22)
Duration of procedure: minutes, median, IQR	150 (118–177)
Significant intraoperative bleeding > 250 ml or intraoperative blood transfusion—% (n)	4 (6)
Intra-operative blood loss: ml, median, IQR	50 (25–75)
Postoperative length of stay: days, median, IQR	4 (3–5)

ASA American society of anesthesiologist, *ml*: milliliters, *IQR* inter-quartile range, *n* number of patients available, % percentage

on DOAC, 4% (1/25)] and perioperative bridging [patients with bridging, 16% (12/74) and 9% (7/79)], respectively.

One patient developed pulmonary embolism on postoperative day (POD) 12 after SG and was readmitted. She was started on IV heparin drip and discharged after obtaining therapeutic INR. Two patients had more than one early complication after RYGB. Both the patients had initial postoperative bleeding complications that were managed with transfusion of blood products and stopping anticoagulants. One of the patients had surgical evacuation of clots and subsequently developed intra-abdominal abscess that was drained percutaneously. The other patient had poor oral intake due to marginal ulcer that was treated with proton-pump inhibitors for 6 months.

All-cause readmissions within 30 days of surgery occurred in 19 patients (12%). Discharge diagnosis for readmissions in the early postoperative period included postoperative bleeding (n = 9), VTE (n = 1), anastomotic leak (n = 2), poor oral intake requiring IV hydration/endoscopic intervention (n = 3), marginal ulcer (n = 2), anastomotic stricture (n = 1), and acute renal failure managed with IV hydration (n = 1). Early postoperative outcomes (< 30 days) are summarized in Table 4.

Discussion

This study aimed to evaluate the prevalence of early postoperative morbidity in chronically anti-coagulated patients undergoing primary laparoscopic bariatric surgery at our institution. The primary findings of this study are that through early postoperative period: (1) the prevalence of intraoperative and postoperative hemorrhagic complications was relatively higher and was noted in six patients (4%) and 19 patients (12%), respectively; (2) one patient (0.6%) developed pulmonary embolism. Additionally, these patients also experienced higher composite morbidity (21.6%) and 30-day readmissions (12.4%) when compared to national averages for non-CAT patients undergoing bariatric surgery [18].

Periprocedural management of patients on CAT requires a fine balance to prevent thrombotic and hemorrhagic complications [1]. These patients constitute a high-risk cohort, due to their associated comorbidities. This was reflected by a higher median age adjusted Charlson comorbidity index of 3 in our population as well. The higher risks for thrombotic and hemorrhagic events in the early postoperative period in the CAT patients can be broadly divided into patient-related and surgical risk factors. Patient characteristics including morbid obesity, history of multiple or severe thrombophilia, recent history (<3 months) of VTE, recent (<6 months) stroke or TIA, mechanical heart valve, $CHADS_2$ score > 4, need for interruption of anticoagulation, and duration of procedure impart a higher thromboembolic risk [5, 13]. Previous history of bleeding especially with invasive procedures, administration of anticoagulants with concomitant anti-platelet agents and non-steroidal anti-inflammatory drugs, and the type of invasive procedure performed confers increased bleeding risks during the early postoperative period [19-23]. In addition, altered gastrointestinal anatomy in patients undergoing bariatric surgery may influence pharmacokinetics of anticoagulants. Reduced caloric intake, decreased and unavailable absorptive surfaces, alkaline pH in the gastric pouch, and increased transit time in RYGB are some of the factors responsible for decreased absorption of anticoagulants [8–10].

One patient (0.65%) in our study developed pulmonary embolism in the early postoperative period. This is similar

Table 4Early postoperative complications (\leq 30 days) in 153 patients

30-day outcomes	LRYGB (<i>n</i> = 79)	LSG (<i>n</i> = 63)	LAGB (<i>n</i> = 11)	Composite $(n = 153)$
30 day composite complications, $\%$ (<i>n</i>)	23 (18)	19 (12)	27 (3)	21 (33)
Postoperative bleeding complications, $\%$ (<i>n</i>)	15 (12)	8 (5)	18 (2)	12 (19)
Intra-abdominal bleeding, n	7	3	0	10
Mx by Reoperation and transfusion/stopping anticoagulation	4	1	0	5
Mx with transfusion/stopping anticoagulation	3	2	0	5
Intra-luminal bleeding, n	5	1		6
Mx with reoperation and transfusion/stopping anticoagulation	2	0	0	2
Mx by stopping anticoagulation/conservative management	3	1	0	4
Port site/abdominal wall hematoma, n	0	1	2	3
Requiring transfusion	0	1	1	2
Mx by Stopping anticoagulation/conservative management	0	0	1	1
Major Complications, $\%$ (<i>n</i>)	1 (1)	6 (4)	0 (0)	3 (5)
Venous Thromboembolism, n	0	1	0	1
Anastomotic/sleeve leak requiring surgical intervention, n	0	3	0	3
Organ space SSI requiring percutaneous drainage/reoperation, <i>n</i>	1	0	0	1
Minor complications, $\%$ (<i>n</i>)	9 (7)	5 (3)	9 (1)	7(11)
Poor oral intake requiring IV hydration/enteral access, n	2	1	0	3
Marginal ulcer diagnosed on EGD, n	3	0	0	3
Stricture diagnosed on EGD, n	1	0	0	1
Pneumonia requiring antibiotics, <i>n</i>	1	0	0	1
Port site seroma, <i>n</i>	0	0	1	1
Anemia managed with transfusion, n	0	1	0	1
Acute renal failure managed with IV hydration, n	0	1	0	1
30 day readmissions, $\%$ (<i>n</i>)	15 (12)	11 (7)	0 (0)	12 (19)
Postoperative bleeding, n	7	2	0	9
VTE, n	0	1	0	1
Anastomotic leak, n	0	2	0	2
Poor oral intake requiring IV hydration/intervention, n	2	1	0	3
Marginal ulcer, <i>n</i>	2	0	0	2
Anastomotic stricture, n	1	0	0	1
Acute renal failure managed with IV hydration, n	0	1	0	1

LRYGB laparoscopic Roux-en-Y gastric bypass, *LSG* laparoscopic sleeve gastrectomy, *LAGB* laparoscopic adjustable gastric banding, *n* number of patients available, *Mx* managed, *TPN* total parenteral nutrition, *SSI* surgical site infection, *IV* intravenous, *EGD* esophagogastroduodenoscopy, *UTI* urinary tract infection, *n* number of patients available

to what has been previously reported for non-CAT patients undergoing bariatric surgery and might have been a result of our institutional practice for strict and extensive thromboprophylaxis in high-risk patients [24]. Six patients (3.9%) required intraoperative transfusion of blood. Of these, two patients further developed hemorrhagic complication in the early postoperative period. Hemorrhagic complications were noted in 19 patients (12.4%) in the early postoperative period. Majority of these were intraabdominal (52.6%) followed by intra-luminal (31.6%) and port-site bleeding (15.8%). Six patients (31.6%) with postoperative bleeding required surgical intervention while the rest were managed conservatively by either stopping the anticoagulants or blood transfusion. With respect to index surgeries performed, the rate of bleeding complications was 15.2% (n = 12) for RYGB, 8.0% (n = 5) for SG, and 18.2% (n = 2) for LAGB. Both the LAGB patients had port site/abdominal wall hematoma secondary to supratherapeutic INR. Overall, the incidence of hemorrhagic complications in our cohort was similar to what has been previously reported in studies including CAT patients undergoing bariatric surgery. The incidence of early postoperative hemorrhage in these studies ranged from 14 to 28% for RYGB procedures and 6.7% for SG patients [1, 7, 10, 12]. Overall, the incidence of hemorrhagic complications in our cohort was similar to what has been previously reported in studies including CAT patients undergoing bariatric surgery. In our experience, patients who require CAT medication are higher than average risk for postoperative bleeding complications after bariatric surgery. Therefore, careful surgical technique and tissue handling are essential during the surgery. Additionally, close attention to postoperative anticoagulation protocols is required to minimize the risk of bleeding.

Patients requiring CAT who undergo bariatric surgery are a high-risk cohort whose overall morbidity in the early postoperative period was expectedly higher (21.6%) when compared to non-CAT bariatric population [25]. This finding was similar to the composite morbidity reported in earlier studies in bariatric patients on CAT [1, 7, 10, 12]. Additionally, 30-day readmission rates (12.4%) were comparatively higher than the reported national average of 5% [18]. More than 50% of the readmissions were related to postoperative bleeding in our study. Despite a higher risk, the incidence of bleeding related 30-day readmissions was comparatively lower to those reported by Bechtel et al. (5.9 vs 16%) [7].

To our knowledge, this study has the largest series of CAT patients who underwent bariatric surgery reported in literature to date. The study limitations include retrospective nature, use of single academic institution, assessment of only early postoperative outcomes, and absence of a matched control group to compare outcomes with.

Conclusion

In our experience, patients who require chronic anticoagulation medication are higher than average risk for postoperative bleeding complications after bariatric surgery. Careful surgical technique and close attention to postoperative anticoagulation protocols are required to decrease risk. Additionally, all-cause readmission rate for these patients (12%) is higher than the 5% national average. Since, these patients are high risk for readmission, targeting them for additional resources after discharge to prevent readmissions may be warranted.

Compliance with Ethical Standards

Conflict of Interest The authors declare that they have no conflict of interest.

Ethical Approval Statement For this type of study, formal consent is not required.

Informed Consent Statement This study does not require informed consent.

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