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Laparoscopic Versus Open Low Anterior Resection for Rectal Cancer: Results from the National Cancer Data Base

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Abstract

Background—While the use of laparoscopy has increased among patients undergoing colorectal surgery, there is ongoing debate regarding the oncologic equivalence of laparoscopy compared to open low anterior resection (LAR) for rectal cancer.

Methods—The 2010–2011 NCDB was queried for patients undergoing LAR for rectal cancer. Subjects were grouped by laparoscopic (LLAR) versus open (OLAR) technique. Baseline characteristics were compared. Subjects were propensity matched, and outcomes were compared between groups.

Results—A total of 18,765 patients were identified (34.3 % LLAR, 65.7 % OLAR). After propensity matching, all baseline variables were highly similar except for carcinoembryonic antigen (CEA) level. Complete resection was more common in patients undergoing LLAR (91.6 vs. 88.9 %, $p < 0.001$), and statistically significant benefits were observed for gross, microscopic, and circumferential (>1 mm) margins (all $p < 0.001$). There was no difference in median number of lymph nodes obtained (15 vs. 15). Patients undergoing LLAR had shorter lengths of stay (5 vs. 6 days, $p < 0.001$) without a corresponding increase in 30-day readmission rates (6 vs. 7 %, $p = 0.02$).

Conclusions—Laparoscopic LAR appears to result in equivalent short-term oncologic outcomes compared to the traditional open approach as measured via surrogate endpoints in the NCDB.

While these results support the increasing use of laparoscopy in rectal surgery, further data are necessary to assess long-term outcomes.

Keywords

Laparoscopy; Low anterior resection; Rectal cancer; Colorectal surgery; National Cancer Data Base

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The NCDB is a joint project of the Commission on Cancer of the American College of Surgeons and the American Cancer Society. The data used in the study are derived from a de-identified NCDB file. The American College of Surgeons and the Commission on Cancer have not verified and are not responsible for the analytic or statistical methodology employed or the conclusions drawn from these data by the investigators.

Introduction

Approximately 40,000 new cases of rectal cancer are diagnosed in the USA per year, and the estimated 5-year survival for all stages is 70 %.¹ Despite improvements in chemotherapeutics and radiotherapy, the mainstay of curative treatment remains appropriate surgical resection of the primary tumor, including total mesorectal excision (TME).¹⁻⁵ Yet, complete resection of rectal tumors is often difficult via an anterior approach due to limited visualization of the lower pelvis, making TME with appropriate surgical margins challenging.⁶

The use of laparoscopy has increased over the past decade for patients with colon cancers,^{7, 8} and several trials have demonstrated the equivalent short- and long-term oncologic outcomes for laparoscopic and open approaches.⁹⁻¹² In rectal cancer, however, there remains ongoing debate as to the oncologic equivalence of laparoscopic versus traditional open approaches^{6, 13, 14}; this includes the largest phase III randomized controlled trial comparing laparoscopic versus open resection of rectal cancers, which suggested increased positive margins among patients undergoing laparoscopic low anterior resection (LAR) for rectal cancer.⁹ Other trials have belied these findings^{6, 14, 15} and even suggested an oncologic benefit to laparoscopy⁶; however, each of these studies has been limited by the lack of certain disease/treatment-specific variables or inadequate sample size.

The National Cancer Data Base (NCDB) is a program of the Commission on Cancer (CoC) administered jointly by the American College of Surgeons and the American Cancer Society. The CoC estimates that greater than 70 % of all cancer diagnoses in the USA are captured in the NCDB, including data from more than 1,500 cancer institutions and 30 million patients.¹⁶ The purpose of this study was to utilize the NCDB to compare short-term oncologic outcomes following open versus laparoscopic LAR for rectal cancer.

Materials and Methods

The Duke University Institutional Review Board approved this retrospective analysis of the NCDB. The NCDB User File for 2010–2011 was queried to identify patients undergoing LAR for rectal cancer. Patients were identified as having undergone LAR (Facility Oncology Registry Data System procedure codes 30 and 40) for rectal cancer first by identifying all patients treated at an NCDB participating institution for tumors in the rectum with International Classification of Diseases for Oncology, Third Edition (ICD-O-3) topography codes C19.9 and C20.9. Relevant histologic subtypes were selected based on ICD-O-3 histology codes 8140, 8210-1, 8261-3, and 8480-1 (all of which represent adenocarcinomas). Other inclusion criteria included malignant behavior, primary cancer diagnosis, and known status for preoperative chemotherapy/radiation therapy.

Subjects were then classified by laparoscopic (LLAR) versus open (OLAR) technique. Baseline characteristics and outcomes between groups were compared using Pearson's chi-square test for categorical variables and analysis of variance (ANOVA) for continuous variables. Multivariable logistic regression was used to predict factors that were associated with the use of laparoscopy. To control for confounding in the treatment decision to use

laparoscopy, we developed propensity scores, which we defined as the conditional probability of undergoing LLAR. Patients were then matched on these propensity scores, using a 1:1 nearest neighbor algorithm. The following variables were used on our propensity match: patient age, sex, race, Charlson/Deyo comorbidity score, patient census tract education and income levels, tumor size, histologic grade, AJCC T- and N-stages, treatment facility type (academic or community hospital), and use of neoadjuvant chemotherapy and/or radiation therapy. Data on carcinoembryonic antigen (CEA) level was missing in approximately 50 % of subjects and thus was not included in the propensity match. Short-term oncologic and perioperative outcomes were then compared between groups. Our primary outcomes of interest were surgical margins and regional lymph node retrieval. Secondary outcomes included 30-day morbidity, 30-day mortality, and hospital length of stay (HLOS).

Results are reported as median (IQR), proportions (%), and odds ratios (OR, 95 % CI) as applicable, unless otherwise specified. We controlled for type I error at the level of the comparison, and p values <0.05 indicate statistical significance. All statistical analyses were performed using R (The R Foundation for Statistical Computing, version 3.0.1, Vienna, Austria).

Results

A total of 18,765 patients were identified who had undergone LAR for rectal adenocarcinoma, of which 12,335 (65.7 %) were performed open (OLAR) and 6,430 (34.3 %) were performed laparoscopically (LLAR). Baseline characteristics are shown in Table 1. Patients who underwent LLAR were slightly younger (61 vs. 62 years, $p<0.001$). They were also more likely to be white (97.5 vs. 85.8 %, $p<0.001$), have an education above the mean (63.3 vs. 55.9 %, $p<0.001$), have an income above the mean (72.4 vs. 65.4 %, $p<0.001$), and have private insurance (53.6 vs. 46.4 %, $p<0.001$). In addition, patients who underwent LLAR were more likely to be treated at an academic/research or comprehensive community cancer program (as opposed to a community cancer program). There were no differences between groups with regard to preoperative comorbidities.

With regard to tumor characteristics (Table 1), patients who underwent LLAR were more likely to have preoperative T-stage 1 or 2 disease (43.5 vs. 33.9 %, $p<0.001$) and were less likely to have radiographic evidence of nodal involvement (26.0 vs. 30.4 %, $p<0.001$); thus, these patients were also less likely to have received neoadjuvant chemotherapy (30.4 vs. 37.8 %, $p<0.001$) or radiation therapy (31.1 vs. 39.9 %, $p<0.001$). Median CEA levels were lower in patients undergoing LLAR (24 vs. 31 ng/ml, $p<0.001$). There were no differences in tumor grade. Following adjustment with multi-variable logistic regression (Table 2), the following variables were associated with the use of laparoscopy: younger age, education above the median, income above the median, and moderately/poorly differentiated tumors. Tumor size >5 cm, AJCC T-stage 3 and 4, and use of neoadjuvant chemotherapy were associated with open technique.

Following propensity matching, all variables except for insurance status and CEA level were highly similar (Table 3). Propensity-adjusted outcomes are shown in Table 4. Patients who

underwent OLAR and LLAR had the same median number of regional lymph nodes retrieved (15); in fact, there was a small but statistically significant improvement in overall node retrieval for patients undergoing LLAR (IQR 11–21 vs. 10–20, $p<0.001$). Complete (R0) resection was more common in patients who underwent LLAR (91.6 vs. 88.9 %, $p<0.001$). Patients who underwent OLAR were more likely to have positive microscopic margins (3.5 vs. 2.9 %, $p<0.001$), positive macroscopic margins (3.4 vs. 2.2 %, $p<0.001$), and positive circumferential margins within 1 mm (7.8 vs. 5.7%, $p<0.001$).

Notably, despite the fact that there were no differences in preoperative clinical stage between propensity-matched groups (Table 3), patients who underwent OLAR had higher postoperative pathologic stage disease (Table 4). This included higher rates of T-stage 3 or 4 disease (54.1 vs. 50.3 %, $p<0.001$), higher rates of node positivity (38.7 vs. 36.4, $p<0.001$), and higher rates of metastatic disease (6.6 vs. 4.5 %, $p<0.001$). In light of these results, we conducted a sensitivity analysis on the propensity-matched patient cohort. Using a multivariable logistic regression model, we estimated the independent effect of laparoscopic versus open approach on complete resection, our primary endpoint of interest, controlling for pathologic AJCC T, N, and M stages. Following adjustment, LLAR remained associated with a 16.3 % decrease in positive margins (adjusted odds ratio 0.86, 95 % CI 0.75–0.99, $p<0.041$).

Among propensity-matched groups, there were no differences in 30-day mortality (1.3 vs. 1.7 %, $p=0.062$). Patients who underwent LLAR had a shorter length of hospital stay (median 5 vs. 6 days, $p<0.001$) and decrease 30-day readmission rates (6.0 vs. 6.9 %, $p=0.044$).

Discussion

In 2005, Guillou and colleagues reported the results from the CLASICC trial comparing laparoscopic-assisted and open surgery for colorectal cancer.⁹ The authors demonstrated similar short-term oncologic outcomes for patients with colon cancer; however, among patients who underwent LAR for rectal cancer ($n = 193$), positive circumferential resection margins (CRM) were twice as common in the laparoscopic approach (12 vs. 6 %). This was the first randomized controlled trial comparing open and laparoscopic resections that included rectal tumors. While several smaller trials and single-institution reviews have since emerged, all have either been underpowered because of size or have been limited by specific factors such as the fraction of patients undergoing LAR or the exclusion of low rectal tumors.^{6, 13–15, 17} This includes the 2013 COLOR II trial, which demonstrated equivalent rates of complete resection and CRM for patients undergoing laparoscopic surgery for rectal cancers.⁶ Although in this study, laparoscopic resection was associated with lower rates of positive margins among patients with low rectal tumors (5 cm from the anal verge), the majority of these patients (77 vs. 23 %) underwent abdominoperineal resection (APR) rather than LAR. Thus, the CLASSICC trial continues to raise concerns regarding the oncologic justification of laparoscopic LAR.

The American College of Surgeons Oncology Group is currently conducting a randomized controlled trial evaluating laparoscopic-assisted versus open resection for patients with

rectal cancer (ACSOG-Z6051).¹⁸ In this trial, subjects will be randomized not only according to tumor site (i.e., high/middle/low rectum) but also according to planned laparoscopic procedure (i.e., LAR vs. APR). The basis for this trial was the 2011 case-matched prospective analysis in which Baik and colleagues demonstrated similar lymph node retrieval and distal margin positivity rates, as well as improved CRM status, for patients undergoing laparoscopic resection.⁵ Because ACSOG-Z6051 will randomize patients based on planned procedure, it should provide level 1 evidence on an intention-to-treat basis regarding the oncologic equivalence of laparoscopic compared to open LAR. However, results from this study will not become available for some time, and in the interim, it is important to better define the oncologic equivalence of laparoscopic LAR, especially given the increasing use of laparoscopy in colorectal surgery.^{7, 8}

In this study, we utilize the NCDB to compare the short-term oncologic outcomes following laparoscopic versus open LAR for rectal cancer. By adjusting for the propensity to undergo laparoscopic LAR, we are able to match on many—although certainly not all—variables that have traditionally been associated with technique decision (e.g., age, tumor size) or that require standardization/randomization in a clinical trial (e.g., clinical stage, neoadjuvant treatment strategies). We found that LLAR was associated with higher rates of complete resection (91.6 vs. 88.9 %, $p<0.001$), as well as specific improvements in macroscopic, microscopic, and circumferential margin status. There was no difference in median number of lymph nodes retrieved (15 vs. 15), which along with macroscopic margins and CRM is an important surrogate marker for adequate TME.^{19, 20} Despite the similar clinical (preoperative) stages of the two cohorts after propensity matching, patients who underwent OLAR were found to have higher pathologic (postoperative) stage disease (including all T, N, and M stages). There were no differences in the rate of neoadjuvant therapy or in treatment response regression scores. Thus, this may represent unmeasured selection bias, as it is possible that patients with equivalent radiographic staging but other subjectively worrisome findings were preferentially selected for open surgery. It is also possible that the higher preoperative CEA levels among OLAR patients (29 vs. 24 ng/ml) represented patients at risk for disease progression, as CEA has been suggested as “high-risk” factor, particularly among patients with stage II rectal cancer.²¹ Nonetheless, following further adjustment with multivariable logistic regression model, in which we controlled for postoperative pathologic stage, we confirmed laparoscopy as an independent predictor of complete resection.

Moreover, patients who underwent LLAR had shorter lengths of hospital stay (median 5 vs. 6 days, $p<0.001$) and a lower 30-day readmission rates (6.0 vs. 6.9 %, $p=0.044$). There were no differences in 30-day mortality (1.3 vs. 1.7 %, $p=0.062$). These and other improvements in short-term non-oncologic outcomes have been reported previously among patients undergoing laparoscopic colorectal surgery, including earlier return of bowel function,^{22–24} shorter use of narcotics/analgesics,^{23–25} lower perioperative morbidity,^{22, 26, 27} and shorter hospital length of stay.^{24, 25, 27} The improvements that we have identified in short-term oncologic outcomes are modest (approximate 1.5 % absolute increase in complete resection) yet support the growing evidence that laparoscopy provides equivalent oncologic resections for rectal cancer compared to traditional open techniques. The ongoing ACSOG-Z6051 trial

should provide level 1 evidence regarding the comparative effectiveness of laparoscopic versus open LAR for rectal cancer. Until these data become available, we can state only that our findings support the increasing use of laparoscopy in colorectal surgery.

While the NCDB is the largest nationwide clinical cancer database, there are nonetheless limitations to this study that must be acknowledged. First, as this is a retrospective analysis, there exists the possibility for selection bias regarding patients chosen for laparoscopy, as well as observation bias regarding data collection. Second, our analysis is limited by the variables and outcomes captured through the NCDB. Thus, we cannot report on important variables such as tumor location (i.e., distance from the anal verge) and body mass index (BMI), factors which almost certainly affect the decision to select patients for laparoscopic versus open surgery. Third, with regard to adequate TME, we are limited to the surrogate markers such as CRM status and node retrieval. In addition, certain variables such as CEA were underreported and thus could not be included in our propensity match. Lastly, we are unable to comment on other short-term postoperative outcomes such as surgical site infection, wound complications, other major morbidity, and hospital cost, although as previously mentioned, many of these data have previously been reported.^{22–27}

Conclusion

Laparoscopic LAR appears to result in equivalent short-term oncologic outcomes compared to traditional open resection as measured via surrogate endpoints in the NCDB. These results support the increasing use of laparoscopy in rectal surgery and provide further clinical equipoise for the current randomized trials assessing long-term outcomes.

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Table 1

Baseline characteristics of patients undergoing LAR for rectal cancer

Variable	OLAR(n= 12,335)	LLAR(n=6,430)	p value
Patient characteristics			
Age, years (IQR)	62 (53, 72)	61 (52, 71)	<0.001
Female	5,154(41.8%)	2,705(42.1 %)	0.719
Race			0.001
White	10,499 (85.8 %)	5,572 (87.5 %)	
Black	1,090 (8.9 %)	464 (7.3 %)	
Other	644 (5.3 %)	334 (5.2 %)	
Charlson Comorbidity Score			0.343
0	9,250 (75 %)	4,884 (76 %)	
1	2,392 (19.4 %)	1,196(18.6%)	
2	693(5.6%)	350 (5.4 %)	
Education above median	6,459 (55.9 %)	3,789 (63.3 %)	<0.001
Income above median	7,547 (65.4 %)	4,335 (72.4 %)	<0.001
Insurance status			<0.001
Private	5,650 (46.4 %)	3,411 (53.6%)	
Medicare	5,002(41.1 %)	2,378 (37.4 %)	
Medicaid	815(6.7%)	334 (5.2 %)	
Government	102 (0.8 %)	61 (1 %)	
Uninsured	602 (4.9 %)	182(2.9%)	
Tumor characteristics			
Tumor size (mm)	40 (25, 55)	37 (24, 50)	0.069
cT stage element			<0.001
1	1,321 (16.7 %)	922 (22.9 %)	
2	1,358 (17.2 %)	829 (20.6 %)	
3	4,649 (58.7 %)	2,124 (52.7 %)	
4	588 (7.4 %)	159(3.9%)	
cN stage element			<0.001
0	7,002 (69.6 %)	3,948 (74 %)	
1	2,445 (24.3 %)	1,160(21.7%)	
2	614 (6.1 %)	229 (4.3 %)	
Grade			0.536
Well differentiated	1,141 (10.1 %)	556 (9.4 %)	
Moderately differentiated	8,680 (76.5 %)	4,565 (77.2 %)	
Poorly differentiated	1,346(11.9%)	701(11.9%)	
Undifferentiated/anaplastic	186(1.6%)	91(1.5%)	
CEA level (IQR)	31 (15,81)	24 (13, 57)	<0.001
Treatment specifics			
Distance to cancer center (IQR)	10 (4, 23)	10(5,23)	0.739
Treatment facility			<0.001

Variable	OLAR(n= 12,335)	LLAR(n=6,430)	p value
Community Cancer Program	1,530 (12.5 %)	477 (7.5 %)	
Comprehensive Community Cancer Program	6,882 (56.1 %)	3,869 (60.5 %)	
Academic/Research Program	3,847(31.4%)	2,052(32.1 %)	
Neoadjuvant XRT	4,628 (37.8 %)	1,938(30.4%)	<0.001
Neoadjuvant chemo	4,866 (39.9 %)	1,978(31.1%)	<0.001
Days to definitive surgery (IQR)	49 (14, 125)	37(15,117)	<0.001

Table 2

Predictors of laparoscopic technique

Variable	Odds ratio	Upper 95 % CI	Lower 95 % CI	p value
Age (per decade)	0.94	0.90	0.97	<0.001
Female sex	1.00	0.91	1.10	0.948
Race				
Black	0.99	0.83	1.17	0.866
Other	0.98	0.80	1.21	0.877
Charlson/Deyo comorbidity score	0.95	0.87	1.03	0.228
Education above median	1.21	1.09	1.35	0.001
Income above median	1.13	1.00	1.27	0.047
Tumor size (ref < 1 cm)				
1–1.9 cm	0.99	0.78	1.24	0.896
2–4.9 cm	0.84	0.68	1.03	0.095
>4.9 cm	0.75	0.61	0.94	0.01
AJCC T stage (ref=T1)				
T2	1.02	0.88	1.18	0.784
T3	0.81	0.70	0.94	0.004
T4	0.56	0.44	0.71	<0.001
AJCC N stage (ref=N0)				
N1	1.02	0.91	1.14	0.756
N2	0.82	0.67	0.99	0.043
Neoadjuvant RT	0.99	0.80	1.22	0.943
Neoadjuvant chemotherapy	0.76	0.62	0.94	0.011
Tumor grade (ref = well differentiated)				
Moderately differentiated	1.32	1.12	1.55	0.001
Poorly differentiated	1.40	1.14	1.72	0.001
Undifferentiated/anaplastic	1.03	0.67	1.56	0.901
Academic program (vs. community)	0.92	0.84	1.02	0.114

Table 3

Adjusted baseline characteristics following propensity matching

Variable	OLAR(n=6,430)	LLAR(n=6,430)	p value
Patient characteristics			
Age, years (IQR)	61 (52, 71)	61 (52, 71)	0.485
Female	2,681(41.7%)	2,705 (42.1 %)	0.681
Race			0.375
White	5,628 (88.3 %)	5,572 (87.5 %)	
Black	434 (6.8 %)	464 (7.3 %)	
Other	313 (4.9 %)	334 (5.2 %)	
Charlson Comorbidity Score			0.886
0	4,907 (76.3 %)	4,884 (76 %)	
1	1,181(18.4%)	1,196(18.6%)	
2	342 (5.3 %)	350 (5.4 %)	
Education above median	3,844 (63.8 %)	3,789 (63.3 %)	0.571
Income above median	4,383 (72.8 %)	4,335 (72.4 %)	0.680
Insurance			<0.001
Private	3,187(50.3%)	3,411 (53.6 %)	
Medicare	2,472 (39 %)	2,378 (37.4 %)	
Medicaid	371 (5.8 %)	334 (5.2 %)	
Government	56 (0.9 %)	61 (1 %)	
Uninsured	256 (4 %)	182(2.9%)	
Tumor characteristics			
Tumor size (mm)	38 (25, 50)	37 (24, 50)	0.832
cT stage element			0.909
1	913 (22.4 %)	922 (22.9 %)	
2	826 (20.3 %)	829 (20.6 %)	
3	2,178(53.5%)	2,124 (52.7 %)	
4	157 (3.9 %)	159(3.9%)	
cN stage element			0.864
0	3,979 (74.2 %)	3,948 (74 %)	
1	1,165(21.7%)	1,160(21.7%)	
2	219 (4.1 %)	229 (4.3 %)	
Grade			0.301
Well differentiated	538 (9 %)	556 (9.4 %)	
Moderately differentiated	4,674 (78.6 %)	4,565 (77.2 %)	
Poorly differentiated	653(11 %)	701(11.9%)	
Undifferentiated/anaplastic	82(1.4%)	91(1.5%)	
CEA level (IQR)	29(14,71)	24(13,57)	0.007
Treatment specifics			
Distance to cancer center (IQR)	9 (4, 21)	10(5,23)	0.763
Treatment facility			0.647

Variable	OLAR(n=6,430)	LLAR(n=6,430)	p value
Community Cancer Program	505 (7.9 %)	477 (7.5 %)	
Comprehensive Community Cancer Program	3,855 (60.3 %)	3,869 (60.5 %)	
Academic/Research Program	2,038(31.9%)	2,052 (32.1 %)	
Neoadjuvant XRT	1,961(30.7%)	1,938(30.4%)	0.69
Neoadjuvant chemo	1,961(30.8%)	1,978(31.1%)	0.75
Days to definitive surgery (IQR)	37(13, 115)	37(15,117)	0.969

Table 4

Outcomes among propensity-matched groups

Variable	OLAR(n=6,430)	LLAR(n=6,430)	p value
Median number of lymph nodes removed (IQR)	15(11,20)	15(11,21)	<0.001
Positive nodes	2,294 (37.6 %)	2,095 (34.3 %)	<0.001
Median number of positive nodes in N+patients (IQR)	3 (1, 5)	2(1,5)	0.035
Regression score			0.121
1-Complete response	780(51.3%)	676 (46.9 %)	
2-Moderate response	375 (24.7 %)	396 (27.5 %)	
3-Minimal response	257 (16.9 %)	260(18.1 %)	
4-Poor/no response	109(7.2%)	108(7.5%)	
Postoperative staging			
Pathologic T stage			<0.001
T0/is	324 (5.4 %)	390 (6.5 %)	
T1	942 (15.8 %)	1,082(18%)	
T2	1,469(24.7%)	1,506(25.1%)	
T3	2,809 (47.2 %)	2,745 (45.8 %)	
T4	409 (6.9 %)	272 (4.5 %)	
Pathologic N stage			<0.001
NO	3,638(61.3%)	3,807 (63.6 %)	
N1	1,452(24.5%)	1,479(24.7%)	
N2	843 (14.2 %)	701(11.7%)	
Pathologic M stage			<0.001
MO	6,005 (93.4 %)	6,141 (95.5 %)	
M1	425 (6.6 %)	289 (4.5 %)	
Margins			
Distal resection margins			<0.001
Negative	5,947(93.1%)	6,052 (95 %)	
Positive margin -microscopic	223 (3.5 %)	182(2.9%)	
Positive margin -macroscopic	215(3.4%)	139(2.2%)	
Circumferential margin within 1 mm	428 (7.9 %)	315(5.7%)	<0.001
Overall positive margins	610(11.2%)	465 (8.4 %)	<0.001
Short-term outcomes			
30-day mortality	108(1.7%)	84(1.3%)	0.096
30-day readmission	441 (6.9 %)	382 (6 %)	0.037
Hospital LOS (IQR)	6 (4, 8)	5 (4, 7)	<0.001