Association of Complications with Healthcare Utilization and Hospital-Borne Costs Among Patients Undergoing Open Low Anterior Resection Using Curved Cutter Staplers

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Purpose: The ability of curved cutter staplers (CCS) to conform to the complex anatomy of the rectum has led to their widespread use in open low anterior resection (LAR). We describe the incidence of complications and their association with healthcare utilization and hospital-borne costs among patients who underwent open LAR with CCS, with the intent to provide contextual epidemiologic and economic burden data for future evaluations of innovations that may lead to a reduced incidence of complications.

Methods: Retrospective cohort study using Premier Healthcare Database. Studied patients were ≥18 years who underwent inpatient open LAR with CCS between October 1, 2016 and March 30, 2020 (index admission). Complications of interest included anastomotic leak, bleeding, infection, transfusion, and device complications/ adverse incidents during the index admission. Outcomes included index admission hospital length of stay (LOS), non-home discharge status, total operating room (OR) time, total hospital-borne costs, and all-cause readmissions within 30, 60, and 90 days post discharge from index admission. Multivariable regression models were used to compare outcomes between patients with vs without any complication of interest.

Results: The study included 618 patients with a mean age of 61 years, of whom 57% were males. The incidence proportion of any complication during the index admission for open LAR with CCS was 28% (95% CI: [23.9%, 31.0%], n=170). As compared with patients experiencing no complications, those with a complication had higher adjusted mean total hospital costs ($38,159 vs $22,303, p<0.001), non-home discharge status (21.8% vs 9.2%, p=0.004), mean LOS (13 days vs 6 days, p<0.001), and mean OR time (362 mins vs 291 mins, p<0.001). There were no significant differences in all-cause readmissions between patients with vs without complications.

Conclusion: Among patients undergoing open LAR with CCS, over a quarter of patients experienced a complication, resulting in a substantial burden to the healthcare system.

Keywords: anastomotic leak, bleeding, costs, contour curved stapler, radial reload, rectal resection

Introduction

Low anterior resection (LAR) involves the removal of all or part of the rectum.1 Performing LAR is challenging due to the narrow pelvic space, complex anatomy, and goal to preserve autonomic nerves of the urogenital organs.2-4 In some cases, linear staplers may not allow for adequate navigation around the pelvis.2 The ability of curved cutter staplers (CCS), such as Ethicon’s CONTOUR® Curved Cutter Stapler and Medtronic’s radial reloads, to conform to the complex anatomy of the
rectum has led to their widespread use in open LAR, providing deeper access and a safer way to perform a double-stapled anastomosis LAR.  

Despite being in use for over a decade, there is a lack of information on the incidence of peri-operative complications of LAR incorporating CCS. A 2010 study conducted in South Korea on CCS use in mid to low rectal cancer surgery reported complications (anastomosis leakage, bleeding, and wound complication) in approximately 37% of patients. However, no studies have been conducted among the United States (US) population describing the incidence of complications in open LAR incorporating CCS. Therefore, the objectives of this study were to (a) describe the incidence of complications and (b) evaluate the association of complications with healthcare utilization and hospital-borne costs among US patients who underwent open LAR using CCS. With limited technological advancements to CCS in the past 15 years, findings from this study may drive the innovation of these products and help to inform future evaluations of innovations that may lead to a reduced incidence of complications in this population.

Methods

Study Design and Data Source

This was a retrospective cohort study of patients who underwent open LAR incorporating curved cutter staplers in an inpatient setting between October 1, 2016 and March 30, 2020. Data were extracted from the Premier Healthcare Database (PHD), a database containing information on inpatient and outpatient discharges of 213 million unique patients from over 900 geographically diverse US community and teaching hospitals. The PHD contains information on patient demographics, diagnoses, procedures, and information on billed services such as hospital-borne costs, diagnostics and therapeutic services provided, and patient discharge status, among other features. The PHD provides deidentified patient information, which exempted this study from the requirement for Institutional Review Board oversight as dictated by Title 45 Code of Federal Regulations (CFR), Part 46 of the US, specifically 45 CFR 46.101(b)(4).

Study Population

Patients ≥18 years of age who underwent open LAR were identified using International Classification of Diseases, Tenth Revision, Procedure Coding System (ICD-10-PCS: 0DTP0ZZ, 0DTP4ZZ). The first hospitalization meeting these criteria was defined as the index admission. The use of CCS during the index admission was identified through a search of hospital administrative charge master records. The search identified the use of records, such as “contour”, “curved”, “cutter”, “radial”, and “stapler” within the hospital administrative records. The results were then reviewed manually to eliminate any records which did not reflect the use of CCS. The analysis was blinded to the stapler brand/company (Ethicon and Medtronic).

Measures

In-Hospital Complications

Complications were identified during the index admission using ICD-10-PCS, International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes, and healthcare common procedure coding system (HCPCS) codes and included anastomotic leak, bleeding, infections (surgical site, abdominal and blood stream infections), transfusion, and device complications/adverse incidents. The codes used for identification of these complications are presented in Appendix 1.

Covariates

Patient characteristics included age (in years, categorized as 18 to 54, 55 to 64, and ≥65), sex (female/male), race (White, non-White), marital status (married, single, other/unknown), payer category (commercial, Medicare, Other), Elixhauser comorbidities, and the Charlson Comorbidity Index (CCI) score (0, 1 to 2, 3 to 4, and ≥5). Procedural characteristics included year of discharge (2016 through 2020), type of admission (elective/nonelective), and intended surgical approach (open, converted laparoscopic/converted robotic-assisted procedure).

Hospital and provider characteristics included hospital size (up to 99 beds, 100 to 199 beds, 200 to 299 beds, 300 to 399 beds, 400 to 499 beds, and ≥500 beds), urbanicity of hospital (rural/urban), hospital teaching status (yes/no), region (Midwest, Northeast, South, West), and procedural physician specialty (colon/rectal surgery, general or other surgery).

Outcomes

The outcomes of this study included the index admission’s hospital length of stay (LOS, expressed in days), discharge status (discharge to home: yes/no), total operating room (OR) time, total hospital-borne costs (inflation adjusted to 2020 US dollars), and all-cause readmissions within 30, 60, and 90 days (yes/no) post-discharge from index admission. All-cause readmissions were examined in patients for whom
their institution continued to contribute data to the PHD for the specified time period. Patients with zero minutes or >1440 minutes of total OR times were excluded from analyses, affecting only 4% of the total eligible study sample.

**Statistical Analyses**

Descriptive statistics for patient, procedural, and hospital/provider characteristics were presented as mean and standard deviation (SD) for continuous variables and frequency and percentage for categorical variables; chi-square tests were used to compare these characteristics between groups with vs without any complication. Incidence proportions and 95% confidence intervals (CI) were reported for complications. Multivariable regression models were used to compare outcomes between patients with vs without any complication, adjusting for all above-listed covariates. A generalized linear model (GLM) with log link and negative binomial error distribution was used for LOS, GLM with logit link and binomial error distribution was used for all-cause 30-, 60-, and 90-day readmissions and discharge status, and GLMs with log link and gamma error distribution were used for total hospital costs and operating time. Marginal standardization was used to generate multivariable-adjusted outcome estimates for each patient group. A p-value < 0.05 was used to determine statistical significance. All analyses were performed using STATA (StataCorp 2015). To examine the sensitivity of study results to the intended

| Variables             | Overall       | Complications | P-value |
|-----------------------|---------------|---------------|---------|
|                       | N  | %  | N  | %  | N  | %  |         |
| All                   | 618 | 100.0 | 170 | 100.0 | 448 | 100.0 |         |
| Age (years), Mean/SD  | 61 | 13.9 | 63 | 12.9 | 60 | 14.1 | 0.097   |
| Age category (in years) |       |       |       |       |       |       |         |
| 18 to 34               | 31 | 5.0 | 3 | 1.8 | 28 | 6.3 |         |
| 35 to 44               | 44 | 7.1 | 9 | 5.3 | 35 | 7.8 |         |
| 45 to 54               | 119 | 19.3 | 34 | 20.0 | 85 | 19.0 |         |
| 55 to 64               | 167 | 27.0 | 44 | 25.9 | 123 | 27.5 |         |
| 65 to 74               | 161 | 26.1 | 46 | 27.1 | 115 | 25.7 |         |
| 75 and greater         | 96 | 15.5 | 34 | 20.0 | 62 | 13.8 |         |
| Sex                   |       |       |       |       |       |       | 0.730   |
| Female                | 265 | 42.9 | 71 | 41.8 | 194 | 43.3 |         |
| Male                  | 353 | 57.1 | 99 | 58.2 | 254 | 56.7 |         |
| Marital status        |       |       |       |       |       |       | 0.234   |
| Married               | 318 | 51.5 | 81 | 47.6 | 237 | 52.9 |         |
| Single                | 272 | 44.0 | 84 | 49.4 | 188 | 42.0 |         |
| Other/Unknown         | 28 | 4.5 | 5 | 2.9 | 23 | 4.1 |         |
| Race                  |       |       |       |       |       |       | 0.186   |
| White                 | 475 | 76.9 | 127 | 74.7 | 348 | 77.7 |         |
| Black                 | 44 | 7.1 | 18 | 10.6 | 26 | 5.8 |         |
| Other                 | 86 | 13.9 | 20 | 11.8 | 66 | 14.7 |         |
| Unknown               | 13 | 2.1 | 5 | 2.9 | 8 | 1.8 |         |
| Payor category        |       |       |       |       |       |       | 0.051   |
| Commercial            | 224 | 36.2 | 48 | 28.2 | 176 | 39.3 |         |
| Medicaid              | 66 | 10.7 | 21 | 12.4 | 45 | 10.0 |         |
| Medicare              | 268 | 43.4 | 86 | 50.6 | 182 | 40.6 |         |
| Other                 | 60 | 9.7 | 15 | 8.8 | 45 | 10.0 |         |

**Abbreviation:** SD, standard deviation.
The majority of hospitals were in an urban region (90%), located in Southern US (60%), were teaching hospitals (51%), and most were large hospitals (≥500 beds: 43%). Only 39% of the procedural physician specialty was colon/rectal surgery.

Table 2 Clinical Characteristics of Adults Who Underwent Open Low Anterior Resection Incorporating Curved Cutter Staplers with vs without Complications

| Variables                          | Overall |                  | Complications |          | P-value |
|-----------------------------------|---------|-----------------|---------------|---------|---------|
|                                   | N       | %               | N             | %       | N       | %       |
| All                               | 618     | 100.0           | 170           | 100.0   | 448     | 100.0   |
| CCI score                         |         |                 |               |         |         |         |
| 0                                 | 88      | 14.2            | 29            | 17.1    | 59      | 13.2    |
| 1 to 2                            | 234     | 37.9            | 53            | 31.2    | 181     | 40.4    |
| 3 to 4                            | 136     | 22.0            | 35            | 20.6    | 101     | 22.5    |
| 5 and above                       | 160     | 25.9            | 53            | 31.2    | 107     | 23.9    |
| Elixhauser Comorbidities+         |         |                 |               |         |         |         |
| Congestive heart failure          | 36      | 5.8             | 19            | 11.2    | 17      | 3.8     |
| Cardiac arrhythmias               | 54      | 8.7             | 14            | 8.2     | 40      | 8.9     |
| Valvular disease                  | 10      | 1.6             | 5             | 2.9     | 5       | 1.1     |
| Pulmonary circulation disorders   | 5       | 0.8             | 1             | 0.6     | 4       | 0.9     |
| Peripheral vascular disorders     | 32      | 5.2             | 15            | 8.8     | 17      | 3.8     |
| Hypertension, uncomplicated       | 247     | 39.9            | 59            | 34.7    | 188     | 41.9    |
| Hypertension, complicated         | 72      | 11.6            | 41            | 24.1    | 31      | 6.9     |
| Other neurological disorders      | 23      | 3.7             | 13            | 7.6     | 10      | 2.2     |
| Chronic pulmonary disease         | 98      | 15.9            | 31            | 18.2    | 67      | 14.9    |
| Diabetes, uncomplicated           | 65      | 10.5            | 8             | 4.7     | 57      | 12.7    |
| Diabetes, complicated             | 54      | 8.7             | 26            | 15.3    | 28      | 6.3     |
| Hypothyroidism                    | 56      | 9.1             | 21            | 12.4    | 35      | 7.8     |
| Renal failure                     | 53      | 8.6             | 31            | 18.2    | 22      | 4.9     |
| Liver disease                     | 22      | 3.6             | 6             | 3.5     | 16      | 3.6     |
| Metastatic cancer                 | 112     | 18.1            | 27            | 15.9    | 85      | 18.9    |
| Solid tumor without metastasis    | 454     | 73.5            | 120           | 70.6    | 334     | 74.6    |
| Rheumatoid arthritis              | 15      | 2.4             | 4             | 2.4     | 11      | 2.5     |
| Coagulopathy                      | 24      | 3.9             | 13            | 7.6     | 11      | 2.5     |
| Obesity                           | 118     | 19.1            | 45            | 26.5    | 73      | 16.3    |
| Weight loss                       | 60      | 9.7             | 22            | 12.9    | 38      | 8.5     |
| Fluid and electrolyte disorders   | 80      | 12.9            | 37            | 21.8    | 43      | 9.6     |
| Blood loss anemia                 | 13      | 2.1             | 4             | 2.4     | 9       | 2.0     |
| Deficiency anemia                 | 26      | 4.2             | 12            | 7.1     | 14      | 3.1     |
| Alcohol abuse                     | 12      | 1.9             | 6             | 3.5     | 6       | 1.3     |
| Drug abuse                        | 11      | 1.8             | 3             | 1.8     | 8       | 1.8     |
| Depression                        | 74      | 11.9            | 26            | 15.3    | 48      | 10.7    |

Note: *Select comorbidities are presented.
Abbreviation: CCI, Charlson comorbidity index.
Table 3 Procedural, Hospital, and Provider Characteristics of Adults Who Underwent Open Low Anterior Resection Incorporating Curved Cutter Staplers with vs without Complications

| Variables                      | Overall | Complications | P-value |
|--------------------------------|---------|---------------|---------|
|                                | N       | %             | Yes     | No      |        |
| **Year of discharge**          |         |               |         |         |        |
| 2016*                          | 59      | 9.5           | 13      | 7.6     | 46      | 10.3   | 0.324  |
| 2017                           | 203     | 32.8          | 62      | 36.5    | 141     | 31.5   |
| 2018                           | 187     | 30.3          | 43      | 25.3    | 144     | 32.1   |
| 2019                           | 142     | 23.0          | 44      | 25.9    | 98      | 21.9   |
| 2020*                          | 27      | 4.4           | 8       | 4.7     | 19      | 4.2    |
| **Type of admission**          |         |               |         |         |        |
| Elective                       | 509     | 82.4          | 132     | 77.6    | 377     | 84.2   | 0.058  |
| Nonelective                    | 109     | 17.6          | 38      | 22.4    | 71      | 15.8   |
| **Approach**                   |         |               |         |         |        |
| Laparoscopic converted to open  | 48      | 7.8           | 16      | 9.4     | 32      | 7.1    | 0.547  |
| Open                           | 492     | 79.6          | 135     | 79.4    | 357     | 79.7   |
| Robotic converted to open      | 78      | 12.6          | 19      | 11.2    | 59      | 13.2   |
| **Urban or Rural**             |         |               |         |         |        |
| Rural                          | 64      | 10.4          | 15      | 8.8     | 49      | 10.9   | 0.441  |
| Urban                          | 554     | 89.6          | 155     | 91.2    | 399     | 89.1   |
| **Teaching hospital**          |         |               |         |         |        |
| Yes                            | 312     | 50.5          | 86      | 50.6    | 226     | 50.4   | 0.975  |
| No                             | 306     | 49.5          | 84      | 49.4    | 222     | 49.6   |
| **Provider region**            |         |               |         |         |        |
| South                          | 368     | 59.5          | 103     | 60.6    | 265     | 59.2   | 0.935  |
| Midwest                        | 114     | 18.4          | 30      | 17.6    | 84      | 18.8   |
| Northeast                      | 75      | 12.1          | 19      | 11.2    | 56      | 12.5   |
| West                           | 61      | 9.9           | 18      | 10.6    | 43      | 9.6    |
| **Hospital size**              |         |               |         |         |        |
| Up to 99 beds                  | 26      | 4.2           | 7       | 4.1     | 19      | 4.2    | 0.698  |
| 100 to 199 beds                | 56      | 9.1           | 14      | 8.2     | 42      | 9.4    |
| 200 to 299 beds                | 72      | 11.7          | 21      | 12.4    | 51      | 11.4   |
| 300 to 399 beds                | 111     | 18.0          | 30      | 17.6    | 81      | 18.1   |
| 400 to 499 beds                | 90      | 14.6          | 31      | 18.2    | 59      | 13.2   |
| 500 and greater beds           | 263     | 42.6          | 67      | 39.4    | 196     | 43.8   |
| **Procedural physician specialty** |     |             |         |         |        |
| General surgery                | 314     | 50.8          | 82      | 48.2    | 232     | 51.8   | 0.700  |
| Colon/rectal surgery           | 242     | 39.2          | 71      | 41.8    | 171     | 38.2   |
| Other                          | 62      | 10.0          | 17      | 10.0    | 45      | 10.0   |

Note: *Year 2016 included data from October onwards while Year 2020 included data till March.

Incidence of Complications

Incidence proportions of all complications are reported in Table 4. The incidence of any complication during the index admission for open LAR with CCS was 28% (95% CI: [23.9%, 31.0%], n=170). The incidence proportions of each individual complication are as follows: anastomotic leak 9% (95% CI: [6.5%, 10.9%], n=54), bleeding 13% (95% CI: [10.7%, 16.1%], n=83), device or other surgical
Table 4 Incidence Proportion of Complications Among Adults Who Underwent Open Low Anterior Resection Using Curved Cutter Staplers, Premier Healthcare Database (October 2016–March 2020)

| Complications                                      | Overall Sample                  |
|----------------------------------------------------|---------------------------------|
|                                                    | N | %   | 95% Confidence Interval |
| Planned open approach including conversions (N = 618) |    |      |                          |
| All                                                | 170 | 27.5 | 24.0% | 31.0% |
| Anastomotic leak                                    | 54  | 8.7  | 6.5%  | 11.0% |
| Bleeding                                            | 83  | 13.4 | 10.7% | 16.1% |
| Device/other surgical complications                 | 68  | 11.0 | 8.5%  | 13.5% |
| Infection                                           | 43  | 7.0  | 5.0%  | 9.0%  |
| Transfusion                                         | 45  | 7.3  | 5.2%  | 9.3%  |
| Planned open approach only (N = 492)                |    |      |        |       |
| All                                                 | 135 | 27.4 | 23.9% | 30.9% |
| Anastomotic leak                                    | 42  | 8.5  | 6.1%  | 11.0% |
| Bleeding                                            | 65  | 13.2 | 10.5% | 15.9% |
| Device/other surgical complications                 | 50  | 10.2 | 7.8%  | 12.5% |
| Infection                                           | 33  | 6.7  | 4.7%  | 8.5%  |
| Transfusion                                         | 32  | 6.5  | 4.6%  | 8.5%  |

Complications 11% (95% CI: [8.5%, 13.5%], n=68), infection 7% (95% CI: [4.9%, 8.9%], n=43), and transfusion 7% (95% CI: [5.2%, 9.3%], n=45).

Cohort Characteristics by Complications

Based on the incidence of all complications, the study cohort was categorized by presence or absence of any complications, as shown in Table 1 (demographics), 2 (clinical characteristics), and 3 (procedural/hospital/provider characteristics). Patients in each study group were similar with respect to demographic and procedural/hospital/provider characteristics. However, patients with complications had higher prevalence of several comorbidities (Table 2), including congestive heart failure (p<0.001), peripheral vascular disorders (p=0.012), complicated hypertension (p<0.001), other neurological disorders (p=0.001), diabetes complicated (p<0.001) and uncomplicated (p=0.004), renal failure (p<0.001), coagulopathy (p=0.003), obesity (p=0.004), fluid and electrolyte disorders (p<0.001), and deficiency anemia (p=0.030).

Healthcare Utilization and Economic Burden of Complications

The association of complications with healthcare utilization and hospital-borne costs after adjusting for covariates is presented in Table 5. As compared with patients experiencing no complications, those with a complication had higher adjusted mean total hospital costs ($38,159 vs $22,303, p<0.001), non-home discharge status (21.8% vs 9.2%, p=0.004), mean LOS (13 days vs 6 days, p<0.001), and mean OR time (362 mins vs 291 mins, p<0.001). There were no significant differences in all-cause readmissions between patients with vs without complications.

Sub-Analysis

Findings from the sub-analysis restricting the study to only planned open cases (ie, excluding converted cases) are also presented in Tables 4 and 5. Incidence proportions of complications were slightly lower (0.2–0.8 percentage points) among planned open cases relative to the overall study group (Table 4). With respect to the association of complications with the study outcomes, mean incremental differences between patients with vs without complications were generally similar in magnitude and statistical significance among planned open cases relative to the overall study group (Table 5).

Discussion

Complications in open LAR with use of CCS is an understudied area. To the best of our knowledge, this is the first study to describe the incidence of complications in open LAR using CCS in the US. The incidence of complications in the single prior study of CCS by Lee et al was 37%.8 The incidence proportion of complications in this study...
Table 5 Multivariable-Adjusted Comparison of Healthcare Utilization and Hospital-Borne Costs in Patients with vs without Complications

| Outcome                                      | AOR b   | 95% CI       | p-value b | Adjusted Outcomes c                  | 95% CI       |
|----------------------------------------------|---------|--------------|-----------|-------------------------------------|--------------|
|                                               |         |              |           | With Complications e | Without Complications e | Difference  |
| Planned open approach including conversions (N = 618) d |         |              |           |                                     |              |
| Total Hospital Costs e                        | 1.7     | (1.53, 1.91) | <0.0001   | $38,159                             | $22,303      | $15,855  | ($11,764, $19,946) |
| Non-Home Discharge Status                    | 4.9     | (1.69, 14.65)| 0.004     | 21.8                                 | 9.2          | 12.6     | (4.6%, 20.5%) |
| Length of stay                               | 2.1     | (1.83, 2.30) | <0.0001   | 12.9 days                           | 6.3 days     | 6.6 days | (5.3 days, 8.0 days) |
| Operating room time f                        | 1.2     | (1.14, 1.35) | <0.0001   | 362 minutes                         | 291 minutes  | 71 minutes | (43 mins, 100 mins) |
| All-cause Readmission Rate d                 |         |              |           |                                     |              |
| Readmission rate – 30 days                   | 1.5     | (0.96, 2.49) | 0.076     | 26.0                                 | 19.3         | 6.7      | (-0.8%, 14.2%) |
| Readmission rate – 60 days                   | 1.5     | (0.93, 2.32) | 0.097     | 33.7                                 | 26.6         | 7.1      | (-1.4%, 15.8%) |
| Readmission rate – 90 days                   | 1.5     | (0.97, 2.29) | 0.067     | 40.1                                 | 31.9         | 8.1      | (-0.6%, 16.9%) |
| Planned open approach only (N = 492) h        |         |              |           |                                     |              |
| Total Hospital Costs e                        | 1.6     | (1.44, 1.85) | <0.0001   | $35,943                             | $21,966      | $13,977  | ($9798, $18,157) |
| Non-Home Discharge Status                    | 6.1     | (1.65, 22.42)| 0.007     | 26.5                                 | 10.4         | 16.0     | (5.8%, 26.3%) |
| Length of stay                               | 1.9     | (1.72, 2.22) | <0.0001   | 12.7 days                           | 6.5 days     | 6.2 days | (4.7 days, 7.7 days) |
| Operating room time f                        | 1.3     | (1.15, 1.39) | <0.0001   | 343 minutes                         | 270 minutes  | 73 minutes | (42 mins, 104 mins) |
| All-cause Readmission Rate d                 |         |              |           |                                     |              |
| Readmission rate – 30 days                   | 1.7     | (0.95, 2.88) | 0.072     | 25.7                                 | 18.3         | 7.3      | (-0.8%, 15.6%) |
| Readmission rate – 60 days                   | 1.7     | (0.99, 2.73) | 0.051     | 33.9                                 | 25.1         | 8.8      | (-0.1%, 17.7%) |
| Readmission rate – 90 days                   | 1.8     | (1.11, 2.83) | 0.016     | 41.4                                 | 30.2         | 11.2     | (2.1%, 20.5%) |

Notes: *Complications is a composite endpoint consisting of anastomotic leak, bleeding, device/other surgical complications, infections, and transfusion. *Adjusted for demographic, procedural, hospital, and provider characteristics. Multivariable-adjusted outcomes based on recycled prediction method. *Based on 618 adults (≥18 years) who underwent open low anterior resection (including conversions) incorporating curved cutter staplers, Premier Healthcare Database (October 2016 through March 2020). *Adjusted to 2020 United States dollars based on the Medical Care component of the United States Bureau of Labor Statistics Consumer Price Index. Operating room time values trimmed to fall between 30 min and 24 h. Calculated among subset of patients who had hospital-level follow-up data available for the specified time period over which readmissions were measured. *Based on 492 adults (≥18 years) who underwent open low anterior resection (not including conversions) incorporating curved cutter staplers, Premier Healthcare Database (October 2016 through March 2020).

Abbreviations: AOR, adjusted odds ratio; CI, confidence interval.
was found to be 28%; upon further examination of the composite of complications, the incidence of bleeding in this study (13.4%) was higher than that reported in the study by Lee et al (10%). Higher incidence of bleeding in the present study may be because this was a multi-institution study as opposed to the single institution represented by Lee et al. Specifically, patient selection and different surgical techniques undertaken in various hospitals may explain these differences.

This is also the first study to explore the association of complications with various outcomes in patients who underwent open LAR with CCS. The presence of complications was significantly associated with increased total hospital-borne costs (by $15,855). One possible explanation for this may be the higher OR and room and board costs, as significantly longer OR time and LOS were associated with the presence of complications. In addition, patients with complications were more likely to be transferred to skilled nursing facilities or other hospitals upon discharge.

The findings of this study should be interpreted considering its limitations. First, it is well-known that the causes of complications are multifactorial; they are driven by surgeon skill and experience, patient-specific factors such as adhesions from prior surgery, whether the surgery was emergent, and device-specific factors such as the technical demands placed on the surgeon when operating the device. In addition, the use of additional stapling devices (such as a circular stapler used for anastomosis) may also contribute to the findings related to clinical complications. We were unable to account for some of these and other factors in the present analysis. As such, while technological advancements to CCS devices may help to facilitate lower complication rates, similar advancements to other related devices, such as circular staplers, could likely drive substantial improvement in patient outcomes. Second, we deployed a text search strategy to identify the use of CCS, as the use of Unique Device Identifiers has not been widely adopted in retrospective databases. The results of the search were verified by the authors; however, it is possible that devices may be misidentified by an individual hospital’s charge master system. Third, the Premier Healthcare Database does not contain information on the stapling (eg, double stapling) or surgical techniques (eg, protective loop ileostomy) often employed in LAR, the number of charges used, or the height of the anastomosis, which may also have an impact on the incidence of complications. Finally, the findings of this study may not be generalizable to all hospitals and patients within and outside of the US.

**Conclusion**

Among patients undergoing open LAR with CCS, the incidence of complications was high and associated with a substantial burden to the healthcare system. Future studies evaluating the use of CCS along with other related and complementary devices may shed light on the direction for technological improvements to reduce the health system burden of complications in open LAR.

**Author Contributions**

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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**Disclosure**

Pragya Rai is a Postdoctoral Research Associate contracted to Johnson & Johnson. Stephen S Johnston is an employee of Johnson & Johnson. Rusha Chaudhari was an employee of MuSigma, contracted to Johnson & Johnson, during the duration of this study. Elena Naoumchik and Esther Pollack are employees of Ethicon. The authors report no other conflicts of interest in this work.

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