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ORIGINAL RESEARCH

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

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rectum has led to their widespread use in open LAR, providing deeper access and a safer way to perform a double-stapled anastomosis LAR.[5–7]

Despite being in use for over a decade,[8] 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.[5] 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.[9] 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), payor 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

Table 1 Demographic Characteristics of Adults Who Underwent Open Low Anterior Resection Incorporating Curved Cutter Staplers with vs without Complications

Variables	Overall		Complications				P-value
			Yes		No		
	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	
Age category (in years)							0.097
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.

surgical approach, a post-hoc sub-analysis was also performed restricting the study to only planned open cases (ie, excluding converted cases).

Results

Baseline Characteristics

Overall patient, procedural, hospital, and provider characteristics are presented in Tables 1–3. The study cohort comprised 618 adults who underwent open LAR incorporating CCS, with a mean age of 61 years (SD = 13.9) and the majority being males (57%), White race (77%), married (52%), on Medicare (43%), with a CCI score of 1 to 2 (38%), and most patients had an elective procedure (82%).

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
			Yes		No		
	N	%	N	%	N	%	
All	618	100.0	170	100.0	448	100.0	
CCI score							0.078
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	<0.001
Cardiac arrhythmias	54	8.7	14	8.2	40	8.9	0.785
Valvular disease	10	1.6	5	2.9	5	1.1	0.108
Pulmonary circulation disorders	5	0.8	1	0.6	4	0.9	0.706
Peripheral vascular disorders	32	5.2	15	8.8	17	3.8	0.012
Hypertension, uncomplicated	247	39.9	59	34.7	188	41.9	0.100
Hypertension, complicated	72	11.6	41	24.1	31	6.9	<0.001
Other neurological disorders	23	3.7	13	7.6	10	2.2	<0.001
Chronic pulmonary disease	98	15.9	31	18.2	67	14.9	0.319
Diabetes, uncomplicated	65	10.5	8	4.7	57	12.7	0.004
Diabetes, complicated	54	8.7	26	15.3	28	6.3	<0.001
Hypothyroidism	56	9.1	21	12.4	35	7.8	0.079
Renal failure	53	8.6	31	18.2	22	4.9	<0.001
Liver disease	22	3.6	6	3.5	16	3.6	0.980
Metastatic cancer	112	18.1	27	15.9	85	18.9	0.373
Solid tumor without metastasis	454	73.5	120	70.6	334	74.6	0.319
Rheumatoid arthritis	15	2.4	4	2.4	11	2.5	0.941
Coagulopathy	24	3.9	13	7.6	11	2.5	0.003
Obesity	118	19.1	45	26.5	73	16.3	0.004
Weight loss	60	9.7	22	12.9	38	8.5	0.095
Fluid and electrolyte disorders	80	12.9	37	21.8	43	9.6	<0.001
Blood loss anemia	13	2.1	4	2.4	9	2.0	0.790
Deficiency anemia	26	4.2	12	7.1	14	3.1	0.030
Alcohol abuse	12	1.9	6	3.5	6	1.3	0.078
Drug abuse	11	1.8	3	1.8	8	1.8	0.986
Depression	74	11.9	26	15.3	48	10.7	0.475

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
			Yes		No		
	N	%	N	%	N	%	
All	618	100.0	170	100.0	448	100.0	
Year of discharge							0.324
2016[a]	59	9.5	13	7.6	46	10.3	
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[a]	27	4.4	8	4.7	19	4.2	
Type of admission							0.058
Elective	509	82.4	132	77.6	377	84.2	
Nonelective	109	17.6	38	22.4	71	15.8	
Approach							0.547
Laparoscopic converted to open	48	7.8	16	9.4	32	7.1	
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							0.441
Rural	64	10.4	15	8.8	49	10.9	
Urban	554	89.6	155	91.2	399	89.1	
Teaching hospital							0.975
Yes	312	50.5	86	50.6	226	50.4	
No	306	49.5	84	49.4	222	49.6	
Provider region							0.935
South	368	59.5	103	60.6	265	59.2	
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							0.698
Up to 99 beds	26	4.2	7	4.1	19	4.2	
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							0.700
General surgery	314	50.8	82	48.2	232	51.8	
Colon/rectal surgery	242	39.2	71	41.8	171	38.2	
Other	62	10.0	17	10.0	45	10.0	

Note: [a]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[a]

Outcome	AOR[b]	95% CI	p-value[b]	Adjusted Outcomes[c]			
				With Complications[c]	Without Complications[c]	Difference	95% CI[c]
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[g]							
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[g]							
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: [a]Complications is a composite endpoint consisting of anastomotic leak, bleeding, device/other surgical complications, infections, and transfusion. [b]Adjusted for demographic, procedural, hospital, and provider characteristics. [c]Multivariable-adjusted outcomes based on recycled prediction method. [d]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). [e]Adjusted to 2020 United States dollars based on the Medical Care component of the United States Bureau of Labor Statistics Consumer Price Index. [f]Operating room time values trimmed to fall between 30 min and 24 h. [g]Calculated among subset of patients for whom hospital-level follow-up data were available for the specified time period over which readmissions were measured. [h]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%).[5] 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 Naoumtchik and Esther Pollack are employees of Ethicon. The authors report no other conflicts of interest in this work.

References

1. Friel CM. Chapter 25 - low anterior resection. In: Evans SRT, editor. *Surgical Pitfalls*. Philadelphia: W.B. Saunders; 2009:273–289.
2. Mari FS, Gasparrini M, Nigri G, et al. Can a curved stapler made for open surgery be useful in laparoscopic lower rectal resections? Technique and experience of a single centre. *Surgeon*. 2013;11(Suppl 1):S23–S26. doi:10.1016/j.surge.2012.10.001
3. Watanabe T, Miyata H, Konno H, et al. Prediction model for complications after low anterior resection based on data from 33,411 Japanese patients included in the National Clinical Database. *Surgery*. 2017;161(6):1597–1608. doi:10.1016/j.surg.2016.12.011
4. Rivadeneira DE, Verdeja JC, Sonoda T. Improved access and visibility during stapling of the ultra-low rectum: a comparative human cadaver study between two curved staplers. *Ann Surg Innov Res*. 2012;6(1):11. doi:10.1186/1750-1164-6-11
5. Lee WS, Lee WY, Chun HK, Yun SH, Cho YB, Yun HR. Curved cutter stapler vs. linear stapler in rectal cancer surgery: a pilot prospective randomized study. *Int J Colorectal Dis*. 2009;24 (11):1327–1332. doi:10.1007/s00384-009-0771-6

6. Isbert C, Jayne D, Germer CT, Boenicke L. Severe mesorectal bleeding after stapled transanal rectal resection (STARR-operation) using the 'contour transtar curved cutter stapler'. *Colorectal Dis*. 2010;12 (5):494. doi:10.1111/j.1463-1318.2010.02185.x
7. Targarona EM, Balague C, Martinez C, Hernandez MP, Trias M. Laparoscopic low rectal anastomosis using a new stapling device: early experience with the contour stapler. *Minim Invasive Ther Allied Technol*. 2008;17(3):155–159. doi:10.1080/13645700802103340
8. Ishii Y, Hasegawa H, Nishibori H, Endo T, Kitajima M. The application of a new stapling device for open surgery (contour curved cutter stapler) in the laparoscopic resection of rectal cancer. *Surg Endosc*. 2006;20(8):1329–1331. doi:10.1007/s00464-005-0633-4
9. Database PH. White paper: Premier Hospital Database (PHD); 2020. Available from: https://products.premierinc.com/downloads/PremierHealthcareDatabaseWhitepaper.pdf. Accessed November 13, 2020.