Ann Surg Oncol (2020) 27:1473–1479
https://doi.org/10.1245/s10434-019-08077-1

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY



ORIGINAL ARTICLE – GASTROINTESTINAL ONCOLOGY

# Staging Laparoscopy is Underutilized in the Management of Gastric Adenocarcinoma

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## ABSTRACT

**Background.** Staging laparoscopy (SL) with peritoneal lavage is usually performed on a separate day from the planned resection and is recommended in patients with gastric adenocarcinoma as it can identify radiographically occult metastases and malignant cytology, thus altering prognosis and treatment. SL can be done on the same day as planned resection (SLSR) or with delayed resection (SLDR). The purpose of this study was to determine utilization of SL and factors associated with SLSR and SLDR, among patients diagnosed with gastric adenocarcinoma.

**Methods.** SEER-Medicare linked data were used to identify patients diagnosed with gastric adenocarcinoma from 2004 through 2013. SL were defined as a laparoscopy that occurred up to 3 months postdiagnosis. Multivariate logistic regression was used to identify factors associated with the utilization of SLSR and SLDR.

**Results.** Of the 5610 patients with gastric adenocarcinoma who underwent a surgical procedure, 733 (13%) had a SL. Utilization of SL increased annually from 6.4% to 22.2% ($p < 0.01$). Receipt of SL was associated with patient demographics, tumor location, and treatment at a National Cancer Institute (NCI) Designated Cancer Center (CC). Of the 733 patients who underwent SL, 475 (65%) received further surgical procedures; 367 (77%) underwent SLSR, while 108 patients (23%) underwent SLDR. Compared with SLSR, SLDR was more common among patients who were younger, treated at an NCI-Designated CC and had proximal tumors.

**Conclusions.** SL for optimal preoperative staging remains underutilized in the management of gastric adenocarcinoma. Expanded use of laparoscopy as a distinct procedure could minimize unnecessary interventions.

In 2018, there were an estimated 26,240 new cases and 10,800 deaths due to gastric adenocarcinoma in the United States.[1] Patients with gastric adenocarcinoma often present with advanced-stage disease. Of those, up to 40% will have peritoneal metastases and another 20% will exhibit positive peritoneal cytology only.[2] Laparoscopy is required to detect radiographically occult peritoneal metastases to stage patients accurately and appropriately triage further therapy.[2,3] Furthermore, patients with microscopic metastatic disease found by cytologic evaluation of peritoneal lavage fluid have a poor prognosis, with no survival advantage associated with primary tumor resection.[4] Peritoneal lavage with cytopathologic analysis, therefore, is advocated to improve the diagnostic yield of staging laparoscopy (SL) and to avoid unnecessary resections.[5,6]

Previous reports have revealed that only 8% of patients diagnosed with gastric cancer undergo SL, despite its demonstrated value and incorporation into treatment guidelines.[7,8] Moreover, SL with peritoneal lavage usually requires that the procedure be performed on a separate date than the planned resection. Intraoperative cytopathology reporting is not routine and, thereby, limits same-day

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First Received: 3 September 2019;
Published Online: 20 November 2019

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resection following SL to detection of gross disease only. We undertook this study to evaluate the use of SL in the setting of newly diagnosed gastric adenocarcinoma in the United States and to document the trends of SL with same-day resection (SLSR) versus delayed resection (SLDR).

## METHODS

The SEER-Medicare database is an electronic linkage of SEER and Medicare that successfully links greater than 94% of patients with cancer aged 65 years in SEER with their Medicare claims data (from 1991 onward). 18 Medicare is a federally funded program that provides health insurance to approximately 97% of the U.S. elderly (aged $\geq$ 65 years). All Medicare-eligible individuals are entitled to Part A coverage (for hospital inpatient care), and approximately 96% also subscribe to Part B coverage (for physician and outpatient care). Beneficiaries can elect to enroll in a health maintenance organization (HMO); Medicare does not receive claims for individual medical conditions for individuals enrolled in HMOs.

Claims data for an additional 5% random sample of Medicare beneficiaries residing in SEER geographic areas are provided. Data were obtained from the linked National Cancer Institute (NCI) Surveillance, Epidemiology and End Results (SEER)-Medicare database. Briefly, the SEER cancer registries collect information including demographics (age, sex, race/ethnicity), date of diagnosis (month/year), tumor characteristics (histology, grade, stage), and vital status for all patients newly diagnosed (incident) with cancer in their catchment areas, which cover approximately 30% of the U.S. population. Medicare is a federally funded health insurance program mainly for persons ages 65 years and older that covers in-patient (Part A) and physician and outpatient (Part B) services. Persons enrolled in fee-for-service (FFS) plans have Medicare claims data.[9,10]

Patients eligible for inclusion in the current study were at least 66 years old at diagnosis with primary gastric adenocarcinoma of intestinal, diffuse type, or signet ring cell carcinoma between January 1, 2004 and December 31, 2013. Patients were excluded if they were diagnosed at the time of death or if they had a prior history of cancer. All patients were required to have complete claims data and, thus, needed to be continuously enrolled in Medicare FFS Parts A and B from 1 year prior to cancer diagnosis through end of follow-up (date of death or December 31, 2014). All patients included in the analytic sample had at least one surgical procedure for gastric cancer occurring between 1 month prior to cancer diagnosis through end of follow-up. This observation period began 1 month prior to diagnosis because there might be slight discrepancies in the data, particularly given the SEER diagnosis date is only month/year. Surgical procedures were defined as laparoscopy, nontherapeutic operation (laparotomy, only; bypass; or wedge resection) or therapeutic operation (total gastrectomy; distal gastrectomy; proximal gastrectomy; or not otherwise specified gastrectomy).

SL was defined as a laparoscopy that occurred 1 month prior to, or up to 3 months post gastric cancer diagnosis that occurred in the absence of, on the same day as, or preceded other identified surgical procedures. To assess utilization of SL with peritoneal lavage, SL were then categorized as "staging laparoscopy with same-day resection" (SLSR) or "staging laparoscopy with delayed resection" (SLDR). All other laparoscopic procedures were considered non-staging for the purposes of this analysis. If a laparotomy was listed on the same day as a therapeutic operation, the patient was classified as having a therapeutic operation. If a patient underwent a laparotomy followed by therapeutic operation at a later date, the patient was classified as receiving a nontherapeutic laparotomy only, as it was assumed that the subsequent therapeutic operation was for palliative purposes.[7] Hospitals where the patient underwent their first gastric surgical procedure were categorized based on NCI-Designated Cancer Center status (no, yes- clinical or comprehensive, and unknown).[10] Comorbidities were assessed using both inpatient and outpatient claims during the 12 months before cancer diagnosis.[11]

Bivariate Chi square tests were used to investigate associations between patient and hospital characteristics, and the utilization of SL and SLDR. Multivariate logistic regression models were constructed to identify factors that were independently associated with utilization of SL and SLDR. Multivariate models only included characteristics that would have been known preoperatively. All statistical tests were two-sided with $\alpha = 0.05$. Statistical analyses were performed using SAS version 9.4 (SAS Institute Inc) software.

## RESULTS

During the study period, 5610 (47%) of the 12,022 eligible patients diagnosed with gastric adenocarcinoma underwent a surgical procedure related to their cancer, of which, 733 (13%) patients underwent a SL (Fig. 1). Of patients who had a SL, 53% ($n = 385$) ultimately had a therapeutic operation for gastric cancer; 35% ($n = 258$) did not have any further surgical procedures, and 13% ($n = 90$) had nontherapeutic operations.

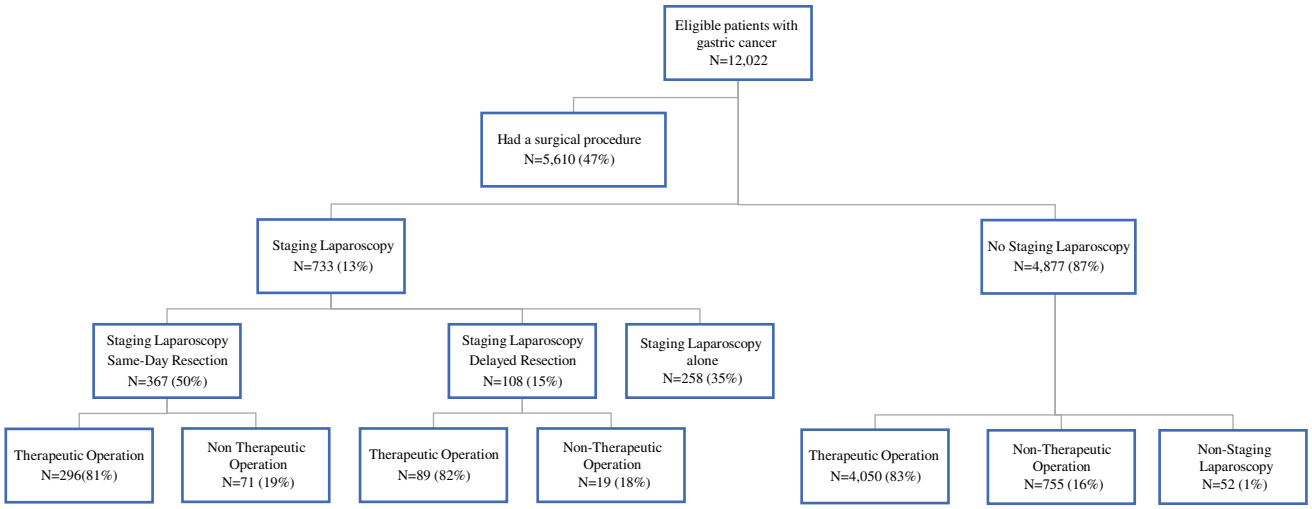


**FIG. 1** Surgical management of gastric cancer patients, SEER-Medicare (2004–2013). Surgical procedures assessed from 1 month before cancer diagnosis through the end of follow-up (date of death or December 31, 2014). Staging laparoscopy: occurred 1 month before or up to 3 months after cancer diagnosis. Nontherapeutic operation: laparotomy, only; bypass; or wedge resection. Therapeutic operation: total gastrectomy; distal gastrectomy; proximal gastrectomy; or not otherwise specified gastrectomy

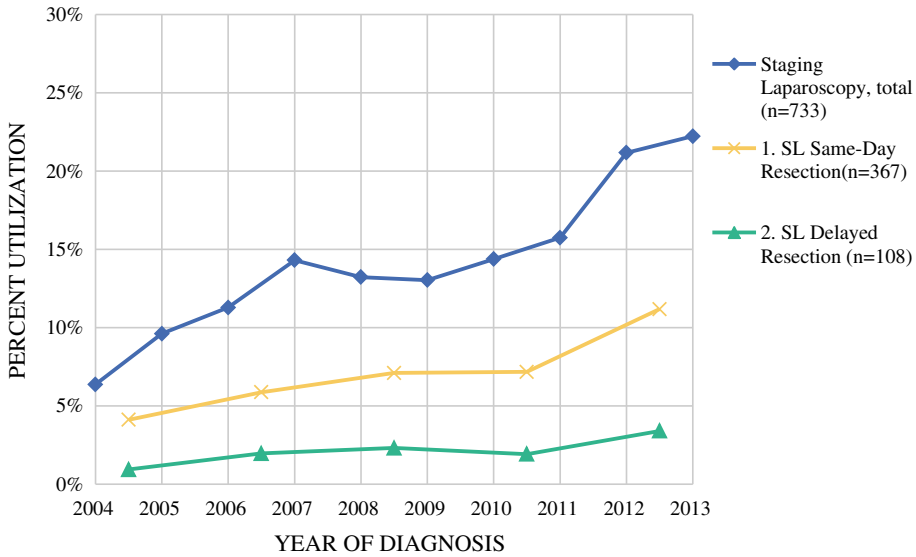


**FIG. 2** Temporal trends in staging laparoscopy (SL) overall and by whether a same-day resection (SLSR) or delayed resection (SLDR)

Annual utilization of SL increased significantly over the study period: from 6.4% in 2004 to 22.2% in 2013 ($p < 0.01$; Fig. 2). The percentage of patients with SLDR increased slightly (18.4–23.3%, $p = 0.84$) over the same period, albeit insignificantly.

Bivariate analysis indicated that SL was significantly more likely among patients who were non-Hispanic white ($p = 0.02$), lived in the northeast ($p < 0.01$), had tumors located in the body or greater curvature (versus antrum/pylorus, $p \leq 0.01$), and received care at an NCI-Designated Cancer Center ($p < 0.01$; Table 1). Independent associations between all these variables, except for geographic region, remained significant in a multivariate logistic regression analysis. On bivariate analysis, the lymph node status, tumor stage, and grade were all significant as well, but only the lymph node status stays significant on the multivariable analysis. Interestingly, SL was found to be more likely among females after adjustment for the other preoperatively known variables ($p = 0.01$). Compared with SLSR, SLDR was less likely among older patients, patients not treated at an NCI-Designated Cancer Center and patients with tumors located in antrum/pylorus (Table 2).

**TABLE 1** Characteristics associated with having a SL among individuals diagnosed with gastric cancer between 2004 and 2013 who underwent at least one gastric procedure, SEER-Medicare

| Characteristic | Total ($N$ = 5610) | Had staging laparoscopy ($N$ = 733) | | Bivariate | Multivariate | | | |
|---|---|---|---|---|---|---|---|---|
| | $n$ | $n$ | % | $p$[a] | OR | 95% CI | | $p$[b] |
| Age, year | | | | 0.15 | | | | 0.05 |
| 66–69 | 976 | 147 | 15.1 | | 1.00 | Ref | | |
| 70–74 | 1417 | 168 | 11.9 | | 0.72 | 0.56 | 0.92 | |
| 75–79 | 1334 | 170 | 12.7 | | 0.84 | 0.66 | 1.08 | |
| 80+ | 1883 | 248 | 13.2 | | 0.92 | 0.73 | 1.17 | |
| Sex | | | | 0.22 | | | | 0.01 |
| Male | 3255 | 410 | 12.6 | | 1.00 | Ref | | |
| Female | 2355 | 323 | 13.7 | | 1.25 | 1.05 | 1.48 | |
| Race/ethnicity | | | | 0.02 | | | | 0.01 |
| Non-Hispanic white | 3404 | 480 | 14.1 | | 1.00 | Ref | | |
| Black | 650 | 81 | 12.5 | | 1.00 | 0.77 | 1.31 | |
| Asian/Pacific Islander | 901 | 107 | 11.9 | | 0.80 | 0.62 | 1.04 | |
| Other/unknown | 655 | 65 | 9.9 | | 0.64 | 0.48 | 0.87 | |
| Geographic residential region | | | | < 0.01 | | | | 0.07 |
| Northeast | 1344 | 221 | 16.4 | | 1.00 | Ref | | |
| West | 2613 | 313 | 12.0 | | 0.84 | 0.68 | 1.04 | |
| Midwest | 561 | 71 | 12.7 | | 0.69 | 0.51 | 0.93 | |
| South | 1092 | 128 | 11.7 | | 0.82 | 0.63 | 1.05 | |
| Tumor location | | | | < 0.01 | | | | < 0.01 |
| Antrum/pylorus | 1743 | 203 | 11.6 | | 1.00 | Ref | | |
| Cardia/fundus | 1453 | 196 | 13.5 | | 1.02 | 0.81 | 1.28 | |
| Body | 505 | 83 | 16.4 | | 1.48 | 1.11 | 1.98 | |
| Lesser curve | 560 | 55 | 9.8 | | 0.86 | 0.62 | 1.19 | |
| Greater curve | 239 | 41 | 17.2 | | 1.57 | 1.08 | 2.30 | |
| Overlapping/other | 1110 | 155 | 14.0 | | 1.24 | 0.99 | 1.57 | |
| National Cancer Institute Designated Center[c,d] | | | | < 0.01 | | | | < 0.01 |
| No | 4909 | 534 | 10.9 | | 1.00 | Ref | | |
| Yes, clinical | 108 | 23 | 21.3 | | 2.24 | 1.36 | 3.67 | |
| Yes, comprehensive | 499 | 162 | 32.5 | | 3.67 | 2.93 | 4.60 | |
| Unknown | 94 | 14 | 14.9 | | 1.26 | 0.58 | 2.72 | |
| T stage[e] | | | | | | | | |
| T0/Tis/T1 | 1286 | 168 | 13.1 | < 0.01 | | | | |
| T2a | 599 | 68 | 11.4 | | | | | |
| T2b/T2, not otherwise specified[f] | 1597 | 173 | 10.8 | | | | | |
| T3 | 1025 | 130 | 12.6 | | | | | |
| T4 | 722 | 80 | 11.1 | | | | | |
| TX | 381 | 114 | 29.9 | | | | | |
| Lymph nodes | | | | < 0.01 | | | | |
| Negative | 2358 | 327 | 13.9 | | | | | |
| Positive | 2861 | 321 | 11.2 | | | | | |
| Unknown | 391 | 85 | 21.7 | | | | | |
| Grade | | | | < 0.01 | | | | |
| Well differentiated | 277 | 32 | 11.6 | | | | | |
| Moderately differentiated | 1544 | 186 | 12.0 | | | | | |
| Poor/undifferentiated | 3284 | 413 | 12.6 | | | | | |

**TABLE 1** continued

| Characteristic | Total ($N$ = 5610) | Had staging laparoscopy ($N$ = 733) | | Bivariate | Multivariate | | |
|---|---|---|---|---|---|---|---|
| | $n$ | $n$ | % | $p$[a] | OR | 95% CI | $p$[b] |
| Unknown | 505 | 102 | 20.2 | | | | |

Adjusted for marital status, comorbidity, and year of diagnosis

*CI* confidence Interval; *OR* odds ratio; *SEER* Surveillance, Epidemiology and End Results; *SL* staging laparoscopy

[a]Chi square $p$-value assessing association between receipt of SL and each listed variable

[b] Logistic regression including all variables that would have been known preoperatively

[c]Hospital where first gastric cancer operation during the study period was performed

[d]Designation status in 2002 for procedures performed in 2004; status in 2005 for procedures performed in 2005–2009; status in 2010 for procedures performed in 2010–2013

[e]American Joint Committee on Cancer, 6th edition

[f]For confidentiality reasons T2, not otherwise specified ($n < 11$) was combined with T2b

## DISCUSSION

Management options and clinical decision making for patients with gastric adenocarcinoma are predicated upon accurate pretreatment staging. The current National Comprehensive Cancer Network (NCCN) guidelines have a 2B recommendation for SL with cytology to evaluate peritoneal spread when considering chemoradiation or surgery in patients with clinical stage T1b or higher.[12] Laparoscopic detection of macrometastatic gastric cancer is sensitive, with a low false-negative detection rate. In cases of detection of radiographically occult metastasis, SL also may allow for expedient referral for systemic therapy and avoidance of nontherapeutic laparotomy. Despite the known benefits of SL, we found its utilization was less than 25%. While this indicates an improvement in the adoption of SL compared with the rate reported previously, utilization remains infrequent.[7] In our study, 35% of patients who underwent a SL did not have an additional operation. This suggests that the laparoscopy likely revealed intra-abdominal metastatic disease or locally unresectable cancer, thus sparing potential surgical morbidity associated with laparotomy. This is consistent with the series from Nassour et al. that showed 34% of patients who underwent SL were found to have distant disease and avoided unnecessary laparotomy.[13]

The other component of SL, besides diagnosing radiographically occult macroscopic disease, is the detection of microscopic malignant cells present in peritoneal washings. According to AJCC of Gastric Carcinoma, positive cytology upstages the patient to M1 category.[14] SL done with cytologic analysis of peritoneal washings requires a separate trip to the operating room for the surgery team and the patient, because most institutions do not offer methods for immediate cytopathology. Upwards of 10% of patients without macroscopic carcinomatosis at time of SL will have positive peritoneal cytology.[3,15,16] Our study demonstrated a low rate of SLDR, suggesting infrequent use of peritoneal lavage and questions whether cytopathologic analysis was performed as part of the staging procedure. Despite the data underscoring the value of peritoneal lavage cytology for detection of microscopic metastatic disease, this practice appears to remain underutilized. This perhaps is due to the low sensitivity of the assay. Per the literature, cytology sensitivity is 19–30% for tumors invading the serosa and approximately 55% for patients with macroscopic peritoneal disease.[17] However, there are novel methods and assays, including molecular testing, that are developing to improve the turnaround time as well as the sensitivity and specificity of cytology.[18]

The current study indicated that non-Hispanic, white race/ethnicity, and being female was associated with higher likelihood of receiving SL. Karanicolas et al. showed a similar demographic profile linked to SL.[7] In contrast, Nassour et al. showed that Hispanic ethnicity was associated with more locally advanced disease and, thus, higher rates of SL based on an institutional series.[13]

Compared with SLSR, SLDR was more common among patients of younger age, with tumors not located in antrum/pylorus, and treatment at NCI Designated CC. This variation by tumor location suggests that surgeons may have conducted a more thorough assessment with peritoneal lavage using SLDR among patients with proximal gastric tumors, which more often are associated with occult metastatic disease.[6] The higher utilization of SLDR at NCI-Designated CC, compared with other centers, underscores the discrepancy in practice patterns across the United

**TABLE 2** Characteristics associated with having a SLDR among individuals diagnosed with gastric cancer between 2004 and 2013 who underwent at least two gastric procedures, SEER-Medicare

| Characteristic | Total ($N$ = 475) | SLDR ($N$ = 108) | | Bivariate | Multivariate | | | |
|---|---|---|---|---|---|---|---|---|
| | $n$ | $n$ | % | $p$[a] | OR | 95% CI | | $p$[b] |
| Age (year) | | | | | | | | 0.02 |
| 66–69 | 82 | 29 | 35.4 | < 0.01 | 1.00 | Ref | | |
| 70–74 | 111 | 28 | 25.2 | | 0.60 | 0.31 | 1.17 | |
| 75–79 | 107 | 24 | 22.4 | | 0.55 | 0.27 | 1.10 | |
| 80+ | 175 | 27 | 15.4 | | 0.33 | 0.17 | 0.65 | |
| Sex | | | | 0.12 | | | | 0.85 |
| Male | 268 | 68 | 25.4 | | 1.00 | Ref | | |
| Female | 207 | 40 | 19.3 | | 0.95 | 0.57 | 1.58 | |
| Race/ethnicity | | | | 0.11 | | | | 0.22 |
| Non-Hispanic white | 282 | 73 | 25.9 | | 1.00 | Ref | | |
| Black | 56 | 12 | 21.4 | | 0.89 | 0.41 | 1.95 | |
| Asian/Pacific Islander/other/unknown | 137 | 23 | 16.8 | | 0.58 | 0.31 | 1.07 | |
| Geographic residential region | | | | 0.37 | | | | 0.93 |
| Northeast | 147 | 39 | 26.5 | | 1.00 | Ref | | |
| West | 214 | 42 | 19.6 | | 0.89 | 0.50 | 1.56 | |
| Midwest | 39 | 11 | 28.2 | | 1.11 | 0.47 | 2.62 | |
| South | 75 | 16 | 21.3 | | 0.86 | 0.41 | 1.80 | |
| Tumor location | | | | < 0.01 | | | | 0.02 |
| Antrum/pylorus | 162 | 25 | 15.4 | | 1.00 | Ref | | |
| Cardia/fundus | 94 | 35 | 37.2 | | 2.78 | 1.45 | 5.34 | |
| Body/lesser curve/greater curve | 129 | 26 | 20.2 | | 1.65 | 0.87 | 3.12 | |
| Overlapping/other | 90 | 22 | 24.4 | | 1.94 | 0.99 | 3.82 | |
| National Cancer Institute Designated Center[c,d] | | | | < 0.01 | | | | < 0.01 |
| No, unknown | 345 | 64 | 18.6 | | 1.00 | Ref | | |
| Yes, clinical or comprehensive | 130 | 44 | 33.9 | | 2.40 | 1.45 | 3.97 | |
| T stage[5] | | | | 0.02 | | | | |
| T0/Tis/T1 | 130 | 17 | 13.1 | | | | | |
| T2 | 177 | 48 | 27.1 | | | | | |
| T3 | 96 | 26 | 27.1 | | | | | |
| T4/TX | 72 | 17 | 23.6 | | | | | |
| Lymph nodes | | | | < 0.01 | | | | |
| Negative, unknown | 240 | 39 | 16.3 | | | | | |
| Positive | 235 | 69 | 29.4 | | | | | |
| Grade | | | | 0.14 | | | | |
| Well/moderately differentiated | 169 | 32 | 18.9 | | | | | |
| Poor, undifferentiated/unknown | 306 | 76 | 24.8 | | | | | |

*CI* confidence Interval; *ICD-O-3* International Classification of Disease for Oncology, 3rd edition; *OR* odds ratio; *SEER* Surveillance, Epidemiology and End Results; *SLDR* staging laparoscopy with delayed resection

[a]Chi square p-value assessing association between receipt of SLDR vs. staging laparoscopy with same-day resection (SLSR) and each listed variable

[b]Logistic regression, including all variables that would have been known preoperatively

[c]Hospital where first gastric cancer surgery procedure was performed

[d]Designation status in 2002 for procedures performed in 2004; status in 2005 for procedures performed in 2005–2009; status in 2010 for procedures performed in 2010–2013

States. To date, there have been no other studies investigating the timing of SL in relation to subsequent surgical procedures in gastric adenocarcinoma.

Using a longitudinal, population database allowed us to examine trends in the use of SL, but it may not adequately reflect the use of SL in all patients diagnosed with gastric cancer in the Unitec States (e.g., persons younger than 65 years or those not enrolled in Medicare FFS). Additionally, we did not directly determine the utilization of peritoneal lavage and cytopathologic analysis at the time of SL, which would provide valuable information on the adoption of this practice over time. The comparison of SL and non-SL groups is likely not an unbiased comparison as we do not fully understand how patients were selected for or against SL in the first place. Moreover, in the SL cohort, we could not discern the exact reason for patients not going on to a therapeutic gastrectomy—whether it was for gross peritoneal disease, positive peritoneal cytology, or local tumor invasion. Similarly, in the group that did not undergo SL, a subset of the patients who had a gastric resection likely may have had occult metastatic disease recognized at laparotomy or diagnosed at final pathology.

## CONCLUSIONS

Although use of SL in patients with gastric adenocarcinoma is increasing annually, this valuable staging technique remains underutilized. SL with peritoneal lavage utilized as a separate, planned procedure before definitive gastric resection is an integral component in the management of patients with gastric cancer. The underwhelming rate of adequate cancer staging in this study underlines the need for strict adherence to evidence-based guidelines. The authors propose clearer communication of the value of SLDR in national guidelines and position statements. Proper staging and identification are paramount for stage-appropriate treatment in gastric cancer patients, especially as more effective therapies are discovered.

**AUTHOR CONTRIBUTIONS** Study conception and design: EMG, ZJB, LE, JMH, JLD; Acquisition of data: EMG, ZJB, LE, SG; Analysis and interpretation of data: EMG, ZJB, LE, SG, JMH, JLD; Drafting of manuscript: EMG, ZJB, LE, SG, JMH, JLD; Critical revisions: EMG, ZJB, LE, SG, LG, JMH, JLD.

**DISCLOSURE** The authors declare they have no conflicts of interest.

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