Abstract

Purpose: Anastomotic leak following colorectal resection surgery is associated with short and long-term negative patient outcomes, prolonged hospitalization, and increased healthcare costs. Various patient related and surgical factors are known to contribute to the development of post-operative anastomotic leaks. This study systematically reviewed the literature to assess the incidence of post-operative leak and identify patient factors associated with the development of leaks.

Methods: Articles published from 1/1/2003 – 8/8/2015 reporting on post-operative anastomotic leak following colorectal resection surgery were identified in the Medline and Embase databases. The rate of post-operative leak, as well as patient and surgical characteristics, were extracted.

Results: Forty-three articles met study inclusion criteria. Within the 14,102 cases, 867 patients experienced anastomotic leak, yielding an average leak rate of 6.1%. Patients were primarily male (57.0%) and had a mean age of 60.2 years. The majority of patients received a stapled anastomosis (70.9%), and most resection surgeries were performed for a diagnosis of cancer (80.7%). Comparison of patient characteristics with and without a post-operative leak revealed male gender, diabetes, open surgical procedures, and sutured anastomoses to be risk factors of anastomotic leak. Patients with anastomotic leak had a longer length of stay in the hospital and higher mortality rate than patients without a leak.

Conclusions: Anastomotic leak remains a major concern in colorectal resection surgery and occurs in approximately 6.1% of cases. Both patient and surgical factors are associated with the development of post-operative anastomotic leak, which is linked to negative patient outcomes and increased mortality.

Background

Colorectal resection surgery is performed to remove diseased or malignant tissue in patients with benign disease or cancer for whom less invasive treatment options have failed [1,2]. Although surgical techniques have evolved over time, significant complications within colorectal resection surgeries remain, most notably the development of post-operative anastomotic leak. At a high level, an anastomotic leak is defined as leakage of the luminal contents from a wound or drain site; leaks can be minor and resolve on their own, or severe and require surgical intervention or other medical procedures to resolve the leakage [3]. There are various levels or grades of anastomotic leakage which are defined based on severity, symptomology, location, and method of detection [3]. The development of post-operative anastomotic leak is one of the most concerning complications in colorectal resection surgery as it is associated with negative patient outcomes including increased risk of abscess or fistula development, greater incidence of infection or sepsis, prolonged hospital stays and a greater risk of post-operative mortality [2,4-7]. Patients who experience anastomotic leak following colorectal resection surgery are also at an increased risk of cancer recurrence, impaired function of pelvic organs, and a permanent stoma [5,8].

Anastomotic leak is estimated to occur in 0.5% to 26% of cases, with low colorectal and coloanal anastomosis posing the greatest risk of leak [2,4-6,9,10]. Surgical factors including operative time, experience of the surgeon, hospital and surgeon case load, and incidence of intraoperative complications have also been shown to be related to the development of anastomotic leaks [2,10-12]. The impact of other factors including laparoscopic versus open surgical techniques, as well as the use of staples versus sutures in anastomoses, remain unclear [2,5,6,10,13]. Additionally, patient related factors including being a smoker, male gender, and increased numbers of comorbidities have also been shown to be associated with higher rates of anastomotic leak [2,10,12-17].

Patients who experience anastomotic leak not only exhibit worse outcomes than patients without a leak, but they also incur greater healthcare costs. Estimates indicate that patients with a leak incur healthcare costs approximately 2-3 fold higher than patients without a leak [4,5]. Elevated healthcare costs are partially due to increased length of stay in the hospital, which is approximately doubled for a leak [4,5]. Treatments for anastomotic leak which can range from antibiotics to reoperation for anastomosis repair or...
diversion also have the potential to dramatically increase the overall
cost of care [4,6].

Considering the impact that anastomotic leak has on patients
undergoing colorectal resection surgery, a clear understanding of the
rate of anastomotic leak, as well as predisposing factors, is needed.
This study conducted a systematic review in the Medline and Embase
databases to provide estimates of the incidence of anastomotic leak
following colorectal resection surgery based on recently published
peer reviewed literature. Focus was placed on the rate of anastomotic
leak following colorectal resection surgery, as well as the operative
and patient specific factors associated with the development of a post-
operative anastomotic leak.

Methods

Search methods and procedures

A systematic search of the Medline and Embase databases was
performed to identify articles reporting on the rate of post-operative
anastomotic leak following colorectal resection surgery. The search
terms and inclusion and exclusion criteria were developed by a panel
of experts on the surgical treatment of gastroenterological diseases
following a preliminary review of the peer-reviewed literature.
References from articles that met study criteria were also reviewed
to expand the search.

Search terms

The Medline and Embase databases were searched for articles
published in English from January 1, 2003 to August 8, 2015 that
reported on the incidence of post-operative leak following colorectal
resection surgery. The search terms included the population being
studied, intervention, and outcome of the review (Table 1).

Types of studies

Only full text articles were included in the review; conference
abstracts, editorials, and letters to the editor were excluded. Article
types in the review included randomized controlled trials (RCTs),
prospective outcome studies, clinical trials, comparative studies,
evaluations, and observational studies.

Study participants

Only articles with adult populations (age ≥ 18 years) that reported
the incidence of post-operative leak after anastomosis in colorectal
surgery were included.

Measures

Study outcomes extracted included study sample size, type(s) of
anastomosis (e.g. staple versus suture), and diagnosis leading
to surgery, patient demographics, comorbidities, mortality rate,
operative characteristics, and length of hospital stay. Post-operative
leak rate was the only required outcome; all other outcomes were
extracted where available.

Screening and reviewing process

All review processes were conducted by two independent
reviewers; any discrepancies between the two reviewers were
reconciled by a third reviewer. The search returned a total of 562
articles. The screening process was initiated with an abstract review;
articles were included if they referenced the prevalence of post-
operative leaks following colon resection surgery. A full text review
was then conducted for those articles that passed the abstract review
(54 articles); articles that did not report the rate of post-operative
leaks following colorectal anastomosis were excluded. The screening
and review phases, led to exclusion of 381 publications leaving 43
studies in the final review (Table 2).

Extracted fields included author, title, date, journal, year of
publication, rate of post-operative leak, and study outcomes. Costs
associated with anastomotic leak was not assessed in this study, as
cost of care was not reported within the articles.

Statistical analyses

For each of the 34 studies included in the review that stated
on the type of anastomosis used frequencies of anastomatic were
reported by each type of anastomosis. Similarly the frequency of
leaks by surgical type were reported for the 34 studies in which the
relationship was described. Finally demographic and operative leak
rates were reported for the leak versus no leak groups in the subset
of 12 articles included in this sample; there were varying numbers
of articles within this subset included based on the demographic
or operative characteristics reported within. Statically significant
differences in leakage rates were assessed by chi square tests of
equality of proportions. Pairwise comparisons were examined where
significant omnibus tests were achieved. Statistical analyses were
conducted with SPSS (version 20, Chicao, IL), and a critical alpha
level of 0.05 was set.

Results

Sample demographics

A total of 14,102 cases were represented within the 43 articles
included in the review. Of the 43 articles studies 19 were conducted in
Europe (44.2%), 18 were from Asia (41.9%), and six were from North
America (13.9%). Overall the sample was primarily male (57%) and
of middle age (60.2 years), reported in 38 and 35 articles respectively
(Table 3). Within the 18 articles that reported BMI, the weighted

Citation: Schiff A, Brady BL, Ghosh SK, Roy S, Ruetzsch C, et al. (2016) Estimated Rate of Post-Operative Anastomotic Leak Following Colorectal
### Table 2: Included Articles

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Title</th>
<th>Journal</th>
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</table>
mean was 23.4, indicating a normal weight for the population (Table 3). The diagnosis leading to colorectal resection surgery was reported in 41 articles; the most common diagnosis was cancer, in 80.7% of cases (11,379). Other diagnoses leading to colorectal resection surgery included inflammatory bowel disease (3.2%), diverticulitis (3.5%), and other (5.2%), which included familial adenomatous, polyposis, polyps, benign tumor, radiation enteritis, stenosis, rectal prolapse, injury, angiodysplasia, reversal of previous surgical procedures, adenoma, ischemic bowel, perforation, and colonic obstruction (Table 3). Presence of a diabetes diagnosis was reported in 11 articles and 12.2% of the sample had diabetes (Table 3). Within the 9 articles that reported smoking status, 35.5% of the sample was found to be a current smoker or have previously smoked (Table 3).

**Operative characteristics**

Where available operative characteristics including type of anastomosis (staple, suture, or other), surgery type (laparoscopic or open), operative time, length of hospital stay, distance of anastomosis to anal verge, and 30 day mortality were extracted from studies.

The type of anastomosis was reported in 39 articles which included 10,885 cases. Stapled anastomosis was used in the majority of cases (70.9%), followed by sutured anastomosis (4.5%), and other (1.8%) which included compression rings or missing data. The type of anastomosis was not stated in remaining 6,815 cases across 4 articles (Table 4). Surgery type was reported in a total of 24 articles.

The weighted mean operative time was 198.6 minutes within the 15 articles that reported duration of surgery. The location of the anastomosis in relation to the anal verge was reported in 16 studies and a mean distance of 6.7 cm was identified within the 4,850 cases. Patients were hospitalized for an average of 14.2 days following surgery (16 articles), and a 30 day mortality rate of 1.0% was identified within the sample (n=6 articles).

**Leak rate**

All 43 articles reported the rate of post-operative leaks. A total of 167 leaks were identified within 14,102 cases, yielding a total leak rate of 6.1% (Table 4). Across the individual studies the rate of leaks ranged from 0.5% to 19.2%.

The leak rate by type of anastomosis was also examined within a subset of 34 articles (9,934 cases) in which both outcomes were reported. Within this subset a total of 579 post-operative leaks were identified, resulting in a leak rate of 5.8%, similar to the overall sample of articles. Staple anastomosis was most common with 9,151 cases; within this group there were 516 leaks producing a leak rate of 5.6%. A total of 534 cases had a suture anastomosis, and 48 of these patients had a post-operative leak (9.0%). The ‘other’ category was comprised of anastomoses that used a compression ring or had missing data regarding closure. Within these 294 cases, a total of 15 leaks were identified post-operatively, yielding a leak rate of 6.0% (Table 4). Chi square tests revealed the rate of leaks in patients with a stapled anastomosis to be significantly lower compared to patients with a sutured anastomosis (p = 0.001).

Similarly the rate of leaks by surgical type were also examined. The rate of leaks within the 4,430 cases who received laparoscopic surgery was 4.0% (total of 179 leaks). The leak rate in the laparoscopic sample

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<tbody>
<tr>
<td>Smith [64]</td>
<td>2007</td>
<td>The efficacy of intraoperative methylene blue enemas to assess the integrity of a colonic anastomosis</td>
<td>BMC Surgery (2007)7:15</td>
</tr>
</tbody>
</table>
was significantly lower than the post-operative leak rate of 6.3% (total 82 leaks) identified in the 1,306 open surgery cases (p=0.001).

**Leak group analysis**

Within the full sample of 43 articles a total of 12 articles were identified that presented patient demographic and surgical characteristics based on post-operative anastomotic leak group (leak versus no leak). Study outcomes were examined using the 4,856 cases within these articles to examine demographic and surgical characteristics associated with anastomotic leak.

The subset of patients in the leak group analysis was similar to the overall study sample. The majority of patients were male (54.6%), and the mean age of the subset was 61.3 years. The subset had a mean BMI of 22.0, and 39.4% and 13.0% had a history of smoking or diabetes respectively. The leak group had a higher percentage of males (68.2% v. 54.8%), smokers (46.3% v. 38.8%), and diabetics (23.4% v. 12.4%) compared to the no leak group (Table 6).

Operative characteristics of the leak group analysis subset were largely similar to the overall study sample. Anastomosis type followed the same trend with stapled anastomosis most commonly used (92.3%), followed by sutured anastomosis (6.6%), and other (1.0%). Laparoscopic surgery was more prevalent in the leak group subset (74% of procedures), as one of the three manuscripts that reported on surgical type only performed laparoscopic procedures. The length of stay was also similar at an average of 13.3 days following anastomosis surgery. Mortality within the leak group analysis subset was higher than the total sample at 2.3% (p=0.03), as was operative time with an average of 235.9 minutes. The distance of the anastomosis to the anal verge was slightly lower in the leak group analysis subset with a mean average of 235.9 minutes. The distance of the anastomosis to the anal verge was compared to the no leak group (Table 6).

Operative characteristics of the leak group analysis subset were largely similar to the overall study sample. Anastomosis type followed the same trend with stapled anastomosis most commonly used (92.3%), followed by sutured anastomosis (6.6%), and other (1.0%). Laparoscopic surgery was more prevalent in the leak group subset (74% of procedures), as one of the three manuscripts that reported on surgical type only performed laparoscopic procedures. The length of stay was also similar at an average of 13.3 days following anastomosis surgery. Mortality within the leak group analysis subset was higher than the total sample at 2.3% (p=0.03), as was operative time with an average of 235.9 minutes. The distance of the anastomosis to the anal verge was slightly lower in the leak group analysis subset with a mean of 4.9 cm. The leak group had a significantly higher rate of sutured anastomoses (10.9% v. 6.3%) and open surgeries (36% v. 25.5%) compared to the no leak group (p<0.01). Operative time and distance to the anal verge was similar between leak groups (Table 6). There was a notable increase in both the length of hospitalization (12.4 v. 20.9 days) and 30 day mortality (1.8% v. 6.2%) in the leak group compared to the no leak group.

Comparison of leak rates by patient and surgical characteristics revealed that males (p<0.0001), patients with diabetes (p<0.0001), patients who had an open surgery (p=0.001), and patients who received a sutured anastomosis (p<0.001) were significantly more likely to experience a post-operative anastomotic leak compared to females, non-diabetics, and stapled anastomoses respectively.

**Discussion**

This study used a systematic review of the Medline and Embase databases to estimate the rate of anastomotic leak following colorectal resection surgery in the recently published literature. A total of 43 articles, corresponding to 14,102 cases were included in the review; the majority of cases underwent colorectal resection for cancer (80.7%). The study sample was primarily male and of middle age (60.2 years), consistent with the demographics of colorectal cancer patients [18]. A total of 867 patients experienced an anastomotic leak,
yielding a study post-operative leak rate of 6.1%, which corresponds with the rate of post-operative leaks reported in multiple prospective and retrospective studies [4,10,19]. Although the overall rate of leaks identified in this study is toward the lower end of published estimates of post-operative leak, the range of post-operative leaks across individual studies within this review (0.5 – 19.2%) is consistent with that of the published literature (0.5 – 26%) [4-6,9,10].

Examination of surgical factors, including anastomosis and surgery type, revealed that patients who received a sutured anastomosis or underwent open surgery were significantly more likely to experience a post-operative leak compared to stapled anastomoses or laparoscopic surgery respectively. The majority of anastomoses included in the study were stapled (70.9%) indicating a preference for the use of staplers in colorectal resection surgeries. Our finding that leaks are more common with sutured anastomoses is a diversion from the literature, which generally reports no difference in leak rate based on anastomosis type [20-22]. Differences in the time period assessed in this review, size of the sample, surgical characteristics (e.g. location of the anastomosis), or study inclusion criteria could account for the differences identified here. Laparoscopic procedures were more common than open surgeries within the sample, although the procedure used was not stated for 48.3% of the sample. Our finding that laparoscopic surgery is associated with a lower rate of post-operative anastomotic leak is not unprecedented [10]. Laparoscopic procedures may cause reduced tissue trauma as compared to open procedures and is associated with faster surgical recovery; previous findings of equality between the procedures are likely related to the study sample including patient and surgeon related factors, as well as the learning curve associated with laparoscopic procedures, that influence the outcome of the surgery [23,24].

In an attempt to assess patient and surgical related factors related to the development of post-operative anastomotic leak, the subset of articles that reported demographic and operative characteristics based on the presence or absence of post-operative anastomotic leak were assessed. This analysis included a total of 12 articles that accounted for a total of 4,856 cases (34.4% of the total sample). The most commonly reported patient characteristics were gender and age, although smoking status and diabetes diagnosis was also assessed within the subset of the sample where they were reported. Consistent with previous reports, there was a greater percentage of males in the leak group compared to the no leak group (54.8% v. 68.2%), which lead to a significantly increased rate of post-operative anastomotic leaks in the male versus female population (8.0% v. 4.9%, p<0.001) [5,10,13]. Although some of the articles included in this review have reported older age to be associated with a greater risk of anastomotic leaks [26,30], there was no difference between the mean age of patients with a leak and patients without a leak in this sample, consistent with other reports [10,12]. There was a trend towards a higher rate of anastomotic leaks in patients who smoked compared to those who did not (8.9% v. 6.7%), but this comparison did not reach statistical significance in our sample. Conversely, patients with diabetes were found to have a significantly greater post-operative anastomotic leak rate compared to individuals without diabetes (9.7% v. 4.8%, p<0.001).

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Table 6: Characteristics by Leak Group.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Articles</th>
<th>Total</th>
<th>Subset Sample</th>
<th>Mean/%</th>
</tr>
</thead>
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<tr>
<td>No Leak</td>
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<td></td>
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<tr>
<td>Male</td>
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<td>2438</td>
<td>54.8%</td>
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<td>2098</td>
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<tr>
<td>Male</td>
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<td>212</td>
<td>68.2%</td>
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<tr>
<td>Female</td>
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<td>108</td>
<td>34.7%</td>
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<tr>
<td>Age</td>
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<tr>
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<td>3431</td>
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<td>4201</td>
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<tr>
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<tr>
<td>Sutured</td>
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<tr>
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<td>Stapled</td>
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<tr>
<td>Open</td>
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<td>36.0%</td>
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<tr>
<td>Laparoscopic</td>
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<td>Operative Time</td>
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<td>Distance to Anal Verge</td>
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<td>492</td>
<td>9</td>
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<tr>
<td>Leak</td>
<td></td>
<td>65</td>
<td>6.2%</td>
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</table>
Similar to the analysis of leak rate by anastomosis type within the larger study sample, we found a significantly higher rate of leaks in the sutured group compared to the stapled group (10.9% v. 6.3%, p=0.001). The rate of ‘other’ types of anastomoses was similar between groups (1.1% in the no leak group v. 0.9% in the leak group), and resulted in a post-operative leak rate of 5.9% in the ‘other’ anastomosis group. We also identified differences in post-operative outcomes across leak groups. In concert with previous findings, the leak group within this subset had a longer duration of hospitalization (20.9 v. 12.4 days) and a higher rate of mortality (6.2% v. 1.8%, p=0.03) compared to the no leak group, indicating worse outcomes within the group of patients who experienced a post-operative anastomotic leak [4,7,13].

This study assessed the rate of intraoperative leaks and factors associated with leaks within a sample of articles identified through systematic review of the Medline database. A study leak rate of 6.1% was found within a sample of 14,102 colorectal resection surgeries. Factors associated with the development of post-operative anastomotic leak were explored, although differences in reporting methodology across studies limited sample sizes and conclusions. Overall the presence of an anastomotic leak was associated with an increased length of hospitalization and higher mortality rates. We were able to identify several surgical factors that were significantly associated with the development of post-operative anastomotic leak, including open versus laparoscopic procedures and use of sutures compared to staples for the anastomosis. We also found a significantly increased anastomotic leak rate within males and patients with a diagnosis of diabetes. Due to the notable impact of anastomotic leak on both patient outcomes and healthcare utilization and costs, further studies to better understand the prevalence of anastomotic leak and predisposing factors are needed.

Conflict of Interest
Ethicon funded this study. A.S., S.K.G, S.R., and E.F. are employees of Johnson & Johnson hold stock. B.L.B and C.R. are employees of Health Analytics, who received support from Johnson & Johnson to conduct this study.

References