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Utility of Closed Suction Pelvic Drains at Time of Large Bowel Resection for Ovarian Cancer

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Abstract

Objective—To test the hypothesis that the use of closed suction pelvic drains placed at time of large bowel resection (LBR) for ovarian cancer (OC) decrease morbidity following anastomotic leak (AL).

Methods—Consecutive cases of LBR for OC between 01/01/1994 and 06/20/2011 were retrospectively identified. Drains were routinely used until bowel movement. AL was defined as: 1) feculent fluid from drains/wound/vagina, 2) radiographic evidence of AL, or 3) AL found at reoperation. Descriptive statistics, Wilcoxon rank-sum, Pearson's chi-square and Fisher's exact test were used.

Results—43 cases met inclusion criteria. AL was characterized by method of diagnosis as follows: change in drain output only (DO, n=8); change in drain output associated with ambiguous clinical signs/symptoms (D-SSX, n=11); or clinical signs/symptoms only (SSX, n=24). The sensitivity of drains in diagnosing AL was 50%. Time to diagnosis was earlier in DO/D-SSX (median 7 vs. 11 days, P=0.003), however, no significant differences were observed in rates of reoperation, length of stay, time to chemotherapy (TTC), and 30- and 90-day mortality between DO/D-SSX and SSX. Comparing cases where no drains were placed (n=5) vs. those with drain (n=38), we observed no differences in outcomes. TTC though statistically significant (47 vs. 59 days, P=0.023) was not clinically significant.

Conclusions—Though a change in drain output correlated with earlier diagnosis, this did not appear to impact overall outcomes. We did not find strong evidence supporting routine prolonged drainage after LBR for OC. Additionally, absence of change in drain output does not rule out presence of AL.

Keywords

large bowel resection; pelvic drain; anastomotic leak; ovarian cancer

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Introduction

Ovarian cancer (OC, including primary peritoneal and fallopian tube cancers) is the most common cause of death among women with gynecologic cancer [1]. The vast majority of OC patients tend to present with advanced stage disease resulting in low overall cure rates. Residual disease after primary debulking surgery is a key predictor of survival [2–5]. OC primarily spreads along peritoneal surfaces commonly involving the cul-de-sac and the bowel. To achieve lowest residual disease, extensive surgery including large bowel resection (LBR), most typical rectosigmoid resection, is essential. In most cases, LBR is performed with primary anastomosis and without placement of a protective stoma [6, 7] in an effort to improve quality of life for the patient.

Anastomotic leak (AL) after LBR is a devastating complication generally requiring emergent reoperation and associated with major morbidity and mortality. In the colorectal literature, postoperative mortality after AL ranges from 7.3 to 16% and accounts for approximately one-third of all postoperative deaths [8–10]. Adjuvant chemotherapy is an essential part of treatment in OC; thus serious postoperative complications cause delays in treatment at best, and at worst prevent initiation of adjuvant therapy and hasten death.

The reported AL rate after pelvic resection for colon cancer varies from 2.8 to 23% [8, 9, 11–18], versus 0.8 to 6.8% in the gynecologic oncology literature [6, 7, 19–21]. Several factors were historically thought to decrease the rate of AL including bowel preparation, antibiotic prophylaxis, diverting stomas, omental wrapping of the anastomosis and intraoperative assessment of anastomotic integrity [22, 23]. Although these procedures still constitute part of current dogma, there is controversy regarding their utility in decreasing the rate and severity of postoperative complications.

Placement of closed suction drains at time of bowel surgery was proposed by Billroth (1881) and later by Sims (1884) [10]. Prophylactic drains are thought to decrease AL by evacuating fluid collections that, once infected, can contribute to abscess formation and subsequent anastomotic breakdown. Theoretically another advantage is the potential for earlier diagnosis of AL, by a change in drain effluent, which could decrease morbidity. Opponents to drains cite that drains are a source of infection and may contribute to abscess and/or fistula formation. In fact, data from the colorectal literature concludes that routine drainage of colonic or rectal anastomoses is of no benefit [24–26]. In a series of 1014 stapled rectal or anal anastomoses, Vignali et al in 1997 [16] failed to show a reduction in AL rate associated with drain use.

These data are relevant in the context of evidence-based multimodal surgical care referred to as “fast-track surgery” or “fast-track methodology”. The underlying concept involves replacing traditional but untested practices of pre-, intra- and postoperative surgical care that may be unnecessary or even harmful [27]. Significant improvements in outcome have been achieved by focusing on the refinement of surgical techniques and perioperative care. However, growing evidence from the colorectal [1, 28–30] and the gynecologic oncology literature [13, 31–33] supports adaption of fast-track surgery to further enhance postoperative recovery and reduce morbidity. Such an approach warrants evaluating the utility of drains at time of LBR in OC.

Our practice has generally been to utilize prophylactic drains after LBR. Closed suction drains are used to both reduce early peri-operative fluid collections which might contribute to infectious morbidity, and to detect anastomotic disruption during return of GI function. The drains are thus maintained until first bowel movement; a clear drain effluent is taken as a sign of continuity of the anastomosis and the drain is pulled at that time.

We sought to determine whether placement of a closed suction drain near large bowel anastomotic sites decreases morbidity by providing immediate drainage and earlier diagnosis of AL. There is little research regarding drains after LBR in OC and extrapolation from the colorectal literature are less relevant because: 1) the scope of OC surgery is larger encompassing most peritoneal surfaces often with other organ resections, 2) the risk factor profile (poor nutritional status, presence of ascites, peritoneal carcinomatosis, marginal performance status, extended operative times, and possible prior cytotoxic therapy) for postoperative morbidity is often higher in OC, and 3) the consequences of AL are profoundly different compared to colon cancer; specifically, there is an essential need for chemotherapy and the surgical challenge of emergent diversion after an extensive debulking surgery is not trivial.

Methods

This study was approved by the Institutional Review Board of Mayo Foundation. All consecutive cases of LBR with primary anastomosis for OC between January 1, 1994 and May 20, 2011 at our Institution were identified. Medical charts were queried for all cases having AL to identify the study cohort. AL was defined as one of the following: 1) feculent fluid from drains, wound, or vagina, 2) radiographic evidence of AL, or 3) AL found at reoperation. Cases of isolated pelvic abscesses near the anastomotic site with no proven communication with the bowel lumen were not included. Patient demographics, perioperative risk factors (including diabetes mellitus, current use of tobacco, history of abdominal and/or pelvic surgery, neo-adjuvant chemotherapy, preoperative albumin, perioperative RBC transfusion, operative time, end-operative body temperature), time to AL diagnosis, patient locale when AL was diagnosed (in hospital vs. after discharge), AL management (antibiotics, total parental nutrition (TPN), radiologic intervention, reoperation), and outcomes (length of stay (LOS), ICU admission, ability to start chemotherapy, time to chemotherapy (TTC), 30- and 90-day mortality) were abstracted.

Time to diagnosis was calculated from the day of initial surgery to the day of AL diagnosis. Delayed reoperation was defined as reoperation after a failed trial of conservative management. Hospital LOS was calculated from AL diagnosis to final discharge. The decision to place a drain was surgeon-dependent and reflective of the practice at the time encompassed by this study: most surgeons placed at least 1 Jackson-Pratt drain adjacent to the anastomotic site at the time of LBR exiting through the lower abdomen. Removal of the drain typically occurred after bowel movement and when drain output was less than 50–100 mL over 24 hours.

We categorized patients by the initial sign or symptom that prompted further diagnostic evaluation as follows: i) by change in drain output only with no clinical signs or symptoms (DO); ii) by change in drain output associated with less than 48 hours of ambiguous clinical signs or symptoms (D-SSX); these patients experienced a change in their clinical status up to 48 hours before AL diagnosis that we could be retrospectively attributed to AL, but did not prompt further diagnostic workup until a change in drain output was noted; and iii) by change in clinical signs and symptoms only (SSX). We performed two primary comparisons to test our hypothesis: 1) Did outcomes differ based upon initial presenting observation (DO vs. D-SSX/SSX and DO/D-SSX vs. SSX), and 2) Were outcomes different based on whether a prophylactic drain was (D+) or was not (D–) placed at LBR (D+ vs. D–). Primary endpoints were time to diagnosis, type of management (conservative vs. surgical) and outcomes.

Descriptive statistics were used to report patient and AL characteristics. Continuous variables were compared using the Wilcoxon rank-sum test; Pearson's chi-squared test or

Fisher's exact test was used to compare categorical variables. A P -value <0.05 was considered statistically significant. Statistical analyses were performed using the JMP software (version 8.0; SAS Institute, Inc.; Cary, NC).

Results

A total of 720 LBR with primary anastomosis were performed during the study period. We identified 43 cases of AL that met inclusion criteria (AL rate 6.0%). After adjusting for case number, the AL rate per surgeon per LBR performed by each surgeon during the study period was comparable across surgeons. Patient demographics and detailed AL characteristics are summarized in Table 1 and Table 2, respectively. No patients had initiated chemotherapy before AL occurrence. Of note, 16 of 43 (37.2%) cases underwent rectosigmoid resection coupled with an additional LBR. No AL case had a diverting stoma created at time of initial surgery. Closed suction deep drains were placed at time of LBR in 38 patients (88.4%, D+) vs. 5 patients without drains (11.6%, D-). For the entire cohort, the median time to AL diagnosis was 8 days (range 4–32). There were only 8 cases whose only presenting sign was a change in quality of drain output (drain only: DO). An additional 11 cases presented with clinical signs or symptoms suggesting an infectious process up to 48 hours before a change in drain output occurred (D-SSX); prior to the change in drain output these were interpreted as ambiguous whereas after the change in drainage quality, they were retrospectively attributed to the AL. The remaining 24 cases were diagnosed by clinical signs or symptoms and specifically had no change in drain output or no drain was present at time of AL (SSX). Overall, drain output, alone or in combination with signs or symptoms, was a factor in establishing a diagnosis of AL in 19 of 38 D+ patients (sensitivity 50%; false negative rate 50%). When restricting to those cases diagnosed by change in drain output only (DO), sensitivity decreased to 21% (8/38). The common clinical signs and symptoms present within 48 hours of diagnosis of AL, are listed in Table 3. Analyzing just those cases diagnosed during the initial hospitalization ($n=30$), the most common clinical signs present within 48 hours of AL diagnosis were leukocytosis (11/25, 44%), tachycardia (10/30, 33.3%), fever (7/30, 23.3%), and hypotension (3/30, 10%).

The vast majority of the AL underwent reoperation (38/43, 88.4%), including 30 immediate and 8 delayed surgeries (median time to reoperation 7.5 days, range 2–14). Initially, 13 cases had a trial of conservative management; however, only 5 patients successfully avoided reoperation (5/13, 38.5%). Nearly all cases (12/13, 92.3%) underwent additional intervention for percutaneous drainage, including 6 cases where the original drain had already been removed and 6 cases where the prophylactic drain provided inadequate control of the leak. Considering 23 D+ cases with the prophylactic drain still in situ at time of AL, only 1 case had sufficient AL control to avoid surgery or radiologically-guided placement of additional drains.

We compared outcomes between cases with a trial of conservative management ($n=13$), vs. immediate surgery ($n=30$). In the conservative group, the median LOS was 20 days (range 11–76). Only 8 of 13 women (61.5%) were eventually able to start chemotherapy with a median time to chemotherapy of 49.5 days. There were 2 (15.4%) postoperative deaths within 90 days of surgery. Comparing the conservative group vs. those who underwent immediate surgery, the latter had a median LOS of 14.5 days (1–58) ($P=0.16$), 22 of 29 (75.9%) were able to initiate chemotherapy ($P=0.46$) at a median time of 48 days ($P=0.86$). There were 6 (20%) deaths within 90 days ($P=1.00$). Considering only the 5 cases successfully managed conservatively vs. those who underwent immediate surgery, median LOS in the conservative group was 12 days (range 11–29) ($P=0.94$), 3 cases (60%) were able to start chemotherapy ($P=0.59$) (median TTC 46 days; $P=0.92$), and there was 1 death within 90 days (20%) ($P=1.00$). Though the number of conservative cases was small, it

appears that conservative management is often unsuccessful, is less commonly associated with starting chemotherapy and does not shorten time to chemotherapy, even in the minority in which it is successful in avoiding reoperation.

We wanted to know if drain output served as an early warning of AL and prevented more serious sequelae after AL. In 8 cases a change in drain output was the exclusive presenting sign of AL (DO). An additional 35 cases presented with either clinical signs or symptoms only or suspicious clinical signs or symptoms later accompanied by a change in output (SSX and D-SSX, respectively). DO cases were in fact diagnosed earlier relative to the D-SSX/SSX group (6.5 vs. 12 days, $P=0.006$) (Table 4a). However, this comparison is confounded by the fact that late AL occurred after discharge at which time drains were removed in most of the cases; most of late leaks were therefore unable to be diagnosed by drain output alone. To address this, we compared only the subgroup of cases diagnosed during the initial hospitalization and observed that the median time to diagnosis was not statistically different between the DO and D-SSX/SSX groups (median 6.5, range 4–10 days vs. 9, 4–32 days, $P=0.07$). Additionally, no significant differences were observed in types of intervention required, LOS, ability to start chemotherapy, TTC and 30- and 90-day mortality (Table 4a). Interestingly, there were no deaths within 90 days of surgery in the DO group (0/8, 0% vs. 8/35, 22.9% in D-SSX/SSX, $P=0.32$); however, limited number of events limited statistical power.

In many cases we noted that suspicious or ambiguous symptoms were present, but a clear drain output lessened clinical suspicion of AL. Two perspectives exist regarding the role drains played in these cases. Perhaps drains served an important auxiliary role as an additional factor when weighing the clinical signs of AL. On the other hand, perhaps the negative drain output erroneously reassured clinicians in the face of suspicious signs (false negative rate as noted earlier was 50%), thus delaying initial workup or treatment. Analyzing all cases with a change in drain output, but now including those with coincident ambiguous signs/symptoms (DO and D-SSX, $n=19$) (Table 4b), against those cases diagnosed purely due to clinical signs or symptoms (SSX, $n=24$), we observed an earlier time to diagnosis in the DO/D-SSX group (7 vs. 14 days, $P<0.001$). Again restricting this to only the subgroup of cases diagnosed in hospital, the DO/D-SSX group still had an earlier time to diagnosis (7 vs. 11 days, $P=0.003$). However, again despite earlier diagnosis, we observed no differences in LOS, ability to start chemotherapy, TTC, 30- and 90-day mortality between the groups (Table 4b). Similarly to the previous comparison, a trend toward more deaths in the group detected by clinical signs or symptoms was noted (6/24, 25% vs. 2/19, 11%; $P=0.27$).

Comparing cases who had drains placed (D+) vs. those without a drain placed (D-) at the original surgery would be the strongest design; however as noted above, only 5 cases did not have a drain placed. Comparing D- ($n=5$) vs. D+ ($n=38$), we observed no differences in time to diagnosis, type of intervention, ability to start chemotherapy or 30- and 90-day mortality (Table 5). Although the D+ group had an earlier median TTC (47 vs. 59 days, $P=0.023$), it was substantially delayed in both groups.

Discussion

Prophylactic drainage of pelvic LBR with primary anastomosis remains a common practice, while drainage of non-pelvic LBR appears ineffective and has long been abandoned in colorectal surgery [23, 26, 34, 35]. In cases of very low anterior resection (anastomosis within 6cm from the anal verge) the data suggest a potential benefit to drainage [16, 23, 28, 32]. Peeters et al. concluded that pelvic drains may offer an earlier detection of AL [13] and Tsujinaka et al. [36] suggested drains may help reduce the severity of consequences

following an AL in colorectal surgery. To our knowledge, no data exist regarding the utility of closed suction pelvic drains following LBR during cytoreductive surgery for OC. In the majority of OC patients, LBR is performed in the pelvis at a level below the peritoneal reflection which can be of variable distance from the anal verge in older female patients but typically at a minimum of 7–8 cm above the anal verge [37]. In the present study, we were unable to find convincing evidence that routine prolonged pelvic drainage after LBR in patients who developed an AL yielded better outcomes in the sense of a shorter LOS, earlier time to chemotherapy or type of intervention required for management.

In our series, drains contributed to the ultimate diagnosis of AL in 50% of relevant cases. This is similar to the sensitivity of 71.4% reported by Tsujinaka et al. [36] but is in stark contrast to the low sensitivity of 5% reported by Urbach et al. [24]. However, our sensitivity decreased to 21% (8/38) when restricted to those cases where DO was the only sign of AL. Although AL cases diagnosed by a change in the drain output had an earlier time to diagnosis, this did not translate into more beneficial outcomes. Specifically, the rate of reoperation was comparable between the DO/D-SSX and SSX groups. Additionally, 4 of the 5 cases successfully managed with conservative approaches required radiologically-assisted placement of additional drain(s) to control the leak, regardless of whether a surgical drain was present. Our results are corroborated by the colorectal literature: Urbach et al. in a systematic review and meta-analysis of the use of drains after colon and rectal anastomoses observed that pus or feces emerged from the drain in only 5% of the AL cases [24] suggesting that drains placed during initial surgery are not successful in controlling the majority of AL. Furthermore, the rates of reoperation reported by Merad et al. (64.7%) [38] and Tsujinaka et al. (52.4%) [36] indicate that drainage is inadequate treatment in most AL. The rates of reoperation in OC are understandably higher as there is immediate need to expeditiously resolve the event in an attempt to prevent chemotherapy delay.

Early diagnosis and management of AL might be expected to correlate with improved outcomes [39, 40]. In our study, though a change in drain output suggestive of AL was associated with an earlier diagnosis in some cases, it did not appear to impact overall outcomes in terms of the need for reoperation, TTC, 30- and 90-day mortality.

Our observations indicate that in many cases subtle signs and symptoms exist prior to ultimate diagnosis of AL; in that regard drains may have played a confirmatory role in forcing clinicians to make or accept a diagnosis. The alternative hypothesis is that drains without a change in output are falsely reassuring even in the face of suspicious symptoms. Supporting the latter is our data that drains carried a 50% false negative rate. In addition, it is striking that, overall, patients with “ambiguous” signs and symptoms (D-SSX) had as many or more signs and symptoms as those with a clinical diagnosis alone (SSX) (Table 3); this suggests that these signs were often misinterpreted possibly due to a reassuring drain output. Although our retrospective design does not allow us to definitively dissect this relationship, it is logical to assume that in many cases the diagnosis was delayed due to a (falsely) reassuring drain output. Without more accurate early indicators of AL such as serum markers, a high index of suspicion is essential to correctly interpret subtle changes associated with AL, regardless of pelvic drainage quality. Mileski et al. showed that the triad of fever, leukocytosis and pelvic or perineal pain was present in 93.8% (15/16) of AL cases after low anterior resection [40]. Similarly, Alberts et al. suggested that the most typical presentation is unexplained fever coupled with tachycardia [41]. Alves et al. studied the natural history of AL after LBR and concluded that there were specific clinical signs and symptoms predictive of AL: a) fever on day 2, b) no return of bowel function by day 4, c) diarrhea before day 7, d) a total of more than 400 mL of fluid in the abdominal drain by day 3, e) renal failure and oliguria on day 3, and f) leukocytosis after day 7 [42]. In our cohort, over half of the AL cases that were diagnosed by change in their clinical status (SSX, 24/43,

55.8%) as well as more than half of the patients diagnosed based on change in the drain output (DO/D-SSX, 11/19, 57.9%) presented with one or more clinical signs or symptoms suggestive of AL up to 48 hours prior to diagnosis. The use of drains is no substitute for clinical astuteness to diagnose AL.

Given the limited value of prolonged drainage, complications attributed to drainage must be considered. Drains can be a potential source of infections, cause bowel perforation, bleeding, and pain, can be difficult to remove, carry the risk of intra-abdominal retention [23, 26, 35, 38] and as noted in this study, may falsely reassure the surgeon and delay AL diagnosis. Surgeons electing to continue prolonged drainage after LBR should consider that assuming the best case scenario (i.e. drains were useful in 19 cases (DO and D-SSX)), drains would be needed in 725 cases to provide benefit to 19 patients (38:1). Considering a lack of benefit on ultimate patient outcome and the potential risks of drains, their use is probably best limited to the initial perioperative period to remove peri-anastomotic fluid collections which could serve as a nidus for local abscess. There appears to be limited benefit in prolonged drain usage.

This study is limited in that it is retrospective and that only 5 cases did not have a drain placed during LBR. As such, comparisons between D– and D+ groups were underpowered. The decision not to use a drain at time of LBR was surgeon-dependent with no information available as to the reasons for not using drains. In conclusion, prophylactic drains placed at time of cytoreduction were associated with a slightly earlier time to diagnosis; however the impact on clinical outcomes was negligible. Specifically, earlier diagnosis by drain was not associated with reduced need for reoperation, less morbidity, shorter time to chemotherapy or improved 30- and 90-day mortality. Our data suggest that routine prolonged use of prophylactic pelvic drains after LBR for OC offers little benefit: their use should be carefully considered in a case-by-case basis. Those electing to use drains should consider limiting their use to the first few postoperative days to reduce fluid collections and evacuate possible contaminants which might play a role in pelvic abscesses in low anastomoses. Further studies including randomized controlled clinical trials are warranted to validate our findings and provide conclusive data on the utility of pelvic drains at time of large bowel resection for ovarian cancer.

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Abbreviations

(OC)	Ovarian cancer
(LBR)	large bowel resection
(AL)	anastomotic leak
(TPN)	total parental nutrition
(LOS)	hospital length of stay
(TTC)	time to chemotherapy

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Research Highlights

- The use of closed suction pelvic drains placed at time of LBR for OC cytoreduction correlated with an earlier time to diagnosis of AL; however, their use was not associated with reduced need for reoperation, less morbidity, shorter time to chemotherapy or improved 30- and 90-day mortality.
- Drains often provided false reassurance in the presence of suspicious signs and symptoms.
- We did not find strong evidence supporting routine prolonged drainage after LBR for OC: their use should be considered in a case-by-case basis and limited to the first few postoperative days.

Table 1

Patient characteristics (N=43).

	n*
Age	64.8 (35.5–84.4)
Body Mass Index	25.7 (19.2–42.7)
<35	36 (83.7)
35	7 (16.3)
Diabetes mellitus type II	4 (9.3)
Current tobacco use	4 (9.8)
History of abdominal and/or pelvic surgery	30 (69.8)
Preoperative albumin (n=21)	4 (2.2–4.9)
<3.5 (g/dL)	6 (27.3)
3.5 (g/dL)	16 (72.7)
Neo-adjuvant chemotherapy	3 (7)
Type of large bowel resection (LBR)	
Rectosigmoid resection (RSR)	24 (55.8)
RSR coupled with additional LBR	16 (37.2)
Other non-pelvic LBR	3 (7)
Anastomotic technique	
stapled	21 (48.9)
handsewn	22 (51.1)
Protective stoma	0 (0)
Closed suction drain(s) placed after LBR (D+)	38 (88.4)
Operative time (minutes)	270 (77–489)
Perioperative RBC transfusion	40 (93)
Time to drain removal (days)	9 (5–15)

* Continuous variables: median (range); categorical variables: absolute count (%).

Table 2

Anastomotic Leak (AL) characteristics (N=43).

	n*
Time to diagnosis of AL (days)	10 (4–33)
Diagnosed before hospital discharge	30 (69.8)
Time to diagnosis (days)	8 (4–32)
Diagnosed after discharge	13 (30.2)
Time to diagnosis (days)	23 (9–33)
Method of diagnosis	
Drain only (DO)	8 (18.6)
In hospital	8 (100)
After discharge	0 (0)
Drain associated with ambiguous clinical signs (D-SSX)	11 (25.6)
In hospital	9 (81.8)
After discharge	2 (12.2)
Clinical signs only (SSX)	24 (55.8)
In hospital	13 (54.2)
After discharge	11 (45.8)
Type of AL	
AL only	21 (48.8)
AL + abscess and/or fistula	20 (46.5)
Fistula only	2 (4.7)
Sepsis	6 (14)
Septic shock	5 (11.6)
Intervention[†]	
Observation only	1 (2.3)
Percutaneous drainage	15 (34.9)
Reoperation	38 (88.4)
Immediate	30
Delayed	8
ICU admission required	15 (34.9)
Hospital length of stay	15 (1–76)
Ability to start chemotherapy (n=42)	30 (71.4)
Time to chemotherapy	48 (25–92)
30- and 90-day mortality	1 (2.3) / 8 (18.6)

* Continuous variables: median (range); categorical variables: absolute count (%).

[†] Patients could have multiple interventions.[‡] Drains were still in place at time of AL diagnosis in 23 patients.

Table 3

Clinical signs and symptoms within 48 hours of diagnosis of anastomotic leak.

	Drain output with ambiguous clinical signs or symptoms* (D-SSX group)	Clinical signs or symptoms (SSX group)
	(n=11)	(n=24)
Fever	7 (63.6)	10 (41.7)
Abdominal pain	6 (54.5)	9 (37.5)
Loose stools/ diarrhea	4 (36.4)	3 (12.5)
Tachycardia	3 (27)	5 (20.8)
Nausea/ Vomiting	-	4 (16.7)
Leukocytosis	2/8 (25)	9/14 (64.3)
Hypotension	-	2 (8.3)
Mental status changes	-	2 (8.3)
Abdominal distention	1 (9.1)	1 (4.2)
Pelvic pain	-	1 (4.2)
No change in clinical status [†]	-	8 (33.3)

* Clinical signs and symptoms that were retrospectively attributed to AL but did not prompt diagnostic workup.

[†] Patients presented with a clinical sign diagnostic of AL (stool per vagina, n=5; stool per wound, n=3) with no appreciable change in their clinical status.

Table 4a

Comparison of outcomes relative to method of diagnosis.

	Drain output only (DO group)	Drain output with ambiguous clinical signs or symptoms and Clinical signs or symptoms (D-SSX and SSX groups)	<i>P</i> -value
	(n=8)	(n=35)	
Time to diagnosis *	6.5 (4–10)	12 (4–33)	0.006
Diagnosed in hospital	8 (100)	22 (62.9)	0.082
Time to diagnosis *	6.5 (4–10)	9 (4–32)	0.07
Intervention			
Conservative	0 (0)	5 (14.3)	0.56
Reoperation	8 (100)	30 (85.7)	0.56
ICU admission required	4 (50)	11 (31.4)	0.42
Hospital length of stay *	19 (8–76)	15 (1–58)	0.47
Ability to start chemotherapy	6 (75)	24/34 (70.6)	1.0
Time to start chemotherapy *	49 (25–53)	47.5 (25–92)	0.3
30-day mortality	0 (0)	1 (2.9)	1.0
90-day mortality	0 (0)	8 (22.9)	0.32

* Median (range) time in days; categorical variables: absolute count (%).

Table 4b

Comparison of outcomes relative to method of diagnosis.

	Drain output only and Drain output with ambiguous clinical signs or symptoms (DO and D-SSX groups)	Clinical signs or symptoms (SSX group)	<i>P</i> -value
	(n=19)	(n=24)	
Time to diagnosis *	7 (4–31)	14 (6–33)	<0.001
Diagnosed in hospital	17 (89.5)	13 (54.2)	0.01
Time to diagnosis *	7 (4–13)	11 (6–32)	0.003
Intervention			
Conservative	1 (5)	4 (17)	0.36
Reoperation	18 (95)	20 (83)	0.36
ICU admission required	9 (47.4)	6 (25)	0.13
Hospital length of stay *	15 (8–76)	15 (1–49)	0.73
Ability to start chemotherapy	15 (79)	15/23 (65.2)	0.49
Time to start chemotherapy *	47.5 (25–60)	48 (31–92)	0.3
30-day mortality	0 (0)	1 (4)	1.0
90-day mortality	2 (11)	6 (25)	0.27

* Median (range) time in days; categorical variables: absolute count (%).

Table 5

Influence of prophylactic drain after LBR (D+) vs. no drain (D-).

	Prophylactic drains placed (D+ group)	No prophylactic drains placed (D- group)	P-value
	(n=38)	(n=5)	
Time to diagnosis *	10 (4–33)	13 (6–32)	0.18
Diagnosed in hospital	26 (68.4)	4 (80)	1.0
Time to diagnosis *	8 (4–15)	12.5 (6–32)	0.08
Intervention			
Conservative	4 (10.5)	1 (20)	0.48
Reoperation	34 (89.5)	4 (80)	0.48
ICU admission required	14 (36.8)	1 (20)	0.64
Hospital length of stay *	15 (1–76)	23 (8–43)	0.95
Ability to start chemotherapy	26/37 (70.3)	4 (80)	1.0
Time to start chemotherapy *	47 (25–64)	59 (48–92)	0.023
30-day mortality	1 (2.6)	0 (0)	1.0
90-day mortality	8 (21.1)	0 (0)	0.56

* Median (range) time in days; categorical variables: absolute count (%).