Analysis of Risk Factors for Anastomotic Leakage after Lower Rectal Cancer Resection, Including Drain Type: A Retrospective Single-Center Study

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Abstract

Background: We investigated the correlations between surgery-related factors and the incidence of leakage after low anterior resection (LAR) for lower rectal cancer.

Methods: A total of 630 patients underwent colorectal surgery between 2011 and 2014 in our department. Of these, 97 patients (15%) underwent LAR and were included in this retrospective study. Temporary ileostomy was performed in each patient.

Results: Anastomotic leakage occurred in 21 patients (21.7%). Univariate analysis showed that operative duration (p=0.0051), transanal hand-sewn anastomosis (p=0.0141), and operation procedure (p=0.0191) were significantly associated with the occurrence of leakage. Multivariate analysis showed that underlying disease (p=0.0440), transanal hand-sewn anastomosis (p=0.0188) and drain type (p=0.0251) were significantly associated with the occurrence of leakage. Propensity-score analysis showed that closed drainage was associated with 6.3 times with anastomotic leakage than open drainage in patients, according to inverse probability of treatment-weighted analysis.

Conclusions: Our results indicate that underlying disease, transanal hand-sewn anastomosis, and drain type may be risk factors for anastomotic leakage after LAR for lower rectal cancer. The notable finding was that the type of drainage was related to the occurrence of anastomotic leakage: closed drainage was correlated with the less volume of postoperative drain discharge than open drain.

Background

Postoperative anastomotic leakage is a major complication after low anterior resection (LAR) for lower rectal cancer. Despite technical improvements and instrument developments, double-stapling anastomosis with circular staples and transanal anastomosis are relatively difficult. The incidence of anastomotic leakage after LAR is 3%–27% [1, 2]. Anastomotic leakage significantly increases postoperative morbidity, requiring prolonged hospital stay and, in some patients, further surgical procedures [3], all of which affect patients' quality of life. In patients with advanced cancer with lymph node metastasis, postoperative adjuvant chemotherapy may be delayed, which could lead to an increased recurrence rate and a poorer prognosis. We previously experienced cases of persistent anastomotic leakage after we changed from open to closed drainage after LAR for lower rectal cancer.

In this study, we investigated the correlations between surgery-related factors, including the type of drain, and the incidence of anastomotic leakage after LAR for lower rectal cancer. Our previous experience suggested that the type of drain may be related to the incidence of postoperative complications. By clarifying these risk factors, we can improve patients' outcomes by preventing the occurrence and severity of anastomotic leakage.

Methods

Between 2011 and 2014, 630 patients underwent colorectal surgery in our department; among these, 149 patients had rectal cancer, excluding rectosigmoid cancer. This retrospective study included all 97 patients who underwent LAR (including intersphincteric resection and total colectomy) at our hospital from 2011 to 2014. Temporary ileostomy was performed in all patients, and no patients received preoperative chemoradiation. Informed consent was obtained from each patient before surgical resection, and the Institutional Review Research Committee for Human Subjects at Kurume University Hospital approved the study (no. 18197). Written informed consent was obtained from each patient prior to enrollment in this study.

The following data were extracted from the clinical records: sex, age, underlying disease (namely, diabetes mellitus, hypertension, coronary artery disease, and renal dysfunction), body mass index (BMI), stage, preoperative albumin value, operation duration, blood loss volume, anastomosis method, lateral lymph node dissection, type of drainage, drainage volume, and occurrence of leakage. The drainage volume was defined as the total amount drained from the day of surgery until the day of drain removal, according to patients' medical records.

The Clavien–Dindo classification system [4] was used to define leakage and included Grade I complications. We confirmed anastomotic leakage with digital examination, anoscopy findings, and enema imaging with iodinated contrast agent.

The drain was classified as one of two types: open (Group O) or closed (Group C). Patients in Group O had both a 6-Fr. duple drain (Kaneka Medical Products, Osaka, Japan) and a 12-Fr. Penrose drain (Fuji Systems Corp., Tokyo, Japan), whereas those in Group C had a 19-Fr. J-VAC drainage system (Johnson & Johnson, New Brunswick, NJ) (Fig. 1). In all patients, we inserted the drains around the anastomosis site.

Statistical analysis

Continuous variables are presented as mean with standard deviation and categorical variables as number and percentage. Independent-samples t-tests were used to evaluate differences between the two groups. Univariate and multivariate logistic regression analyses were performed to explore the factors associated with the presence or absence of leaks. Multivariate logistic models were developed using the backward selection method. Propensity-score analysis was performed to confirm the effect of drain type on leakage. Because the population was unbalanced, the main analysis used inverse probability of treatment weighting (IPTW). Although the population was small, propensity-score matching was used for sensitivity analysis. All statistical analyses were performed with SAS ver. 9.4 (SAS Institute Inc., Cary, NC). A significant difference was defined as a p-value of less than 0.05.

Results

Patients' characteristics

Table 1 summarizes the background clinical characteristics of the patients enrolled in this study. The median age was 64.2 years (range, 34–83 years); 76 patients (78.4%) were men, and 21 (21.6%) were women. The median BMI was 22.6 kg/m^2. An open drain was used in 56 patients (57.7%) and a closed drain in 41 patients (42.3%). The average drainage volume was 765 ml and the average preoperative albumin value was 3.93 g/dL. Fifteen patients (15.5%) underwent lateral lymph node dissection, whereas 82 patients (84.5%) did not. Forty-four patients (45.4%) had underlying disease (with duplicate cases), and 53 patients (54.6%) had no underlying disease.

We performed the following surgical procedures. LAR (in which the anastomosis was located on the anal side of the peritoneal reflection) was performed in 45 patients, ultralow anterior resection (u-LAR: a sphincter-saving procedure for very low-lying rectal cancers, in which anastomosis is performed with the double-stapling technique) was performed in 14 patients, coloanal anastomosis (CAA: a sphincter-saving procedure for very low-lying rectal cancers, in which hand-sewn anastomosis is performed) was performed in six patients, and intersphincteric resection (ISR) was performed in 32 patients. Fifty-nine patients (60.8%) underwent the double-stapling technique, and 38 patients (39.2%) underwent a hand-sewn technique for the anastomosis.

Anastomotic leakage

Anastomotic leakage occurred in 21 patients (21.7%); none developed retrograde infection. The leakage-positive group included 21 patients, and the leakage-negative group included 76 patients (Table 2). We found no significant difference between the groups in age, sex, underlying disease, BMI, intraoperative blood loss volume, preoperative albumin, or lateral lymph node dissection. Although not significantly different, the drainage volume tended to be lower in Group C than in Group O. Significant differences were observed between groups in operation duration (p=0.0026), anastomosis method (p=0.0227), and surgical procedure (p=0.0227).

Table 3 shows the results of univariate and multivariate analyses of the risk factors for leakage in patients who underwent LAR. In univariate analysis, operative duration (p=0.0051), transanal hand-sewn anastomosis (p=0.0208), and operation procedure (p=0.0191) were significantly associated with the occurrence of leakage after LAR. In addition, the leakage incidence was higher among patients with long operative duration for LAR and among those who underwent transanal hand-sewn anastomosis. In multivariate analysis, underlying disease (hazard ratio [HR]: 3.258, 95% confidence interval [CI]: 1.032–10.283; p=0.0440), transanal hand-sewn anastomosis (HR: 5.07, 95% CI: 1.31–19.632; p=0.0188), and drain type (HR: 4.311, 95% CI: 1.2–15.484; p=0.0251) were significantly associated with the occurrence of leakage in patients who underwent LAR. Leakage after LAR occurred more commonly in patients with underlying disease, in those who underwent transanal hand-sewn anastomosis, and in those with closed drainage.

We performed propensity-score analysis to confirm these findings. Because the population was imbalanced, we used IPTW in the main analysis. Although the population was small, we used propensity-score matching. Table 4 shows the propensity-score analysis results (unadjusted HR: 2.161, p=0.1235; adjusted with IPTW, HR: 6.315, p<0.0001; propensity-score matching: HR: 5, p=0.1738). The IPTW analysis revealed a significant difference between results in patients with an open drain versus a closed drain. Closed drainage was associated with a 6.315 times higher incidence of postoperative leakage than open drainage. In the propensity-score matched analysis, the number of patients with open versus closed drainage was imbalanced, so fewer patients were included when matching was performed, and no significant difference was observed. Table 5 shows that the average drainage volume was 954 ml in Group O and 507 ml in Group C; this difference was significant (p < 0.0010). Table 6 shows the percentage of each operation procedure for each type of drain. In the group with open drain (n=56), CAA/ISR was performed in 28 cases (50.0%) and LAR/u-LAR was performed in 28 cases (50.0%). In the closed-drain group (n=41), CAA/ISR was performed in 10 cases (24.4%) and LAR/u-LAR was performed in 31 cases (75.6%). In the open-drain group, the operation method was evenly divided, whereas in the closed-drain group, LAR/u-LAR was performed in 2/3 of procedures.

Discussion

Anastomotic leakage is a major complication after lower rectal surgery and is associated with postoperative morbidity, mortality, functional defects, and oncological outcomes [5, 6]. Several risk factors have been reported for anastomotic leakage after open LAR [7-11], and recent studies have also examined the risk factors for anastomotic leakage after laparoscopic LAR [12-21]. The devices and techniques used for laparoscopic LAR differ from those used in open LAR, suggesting that the risk factors for anastomotic leakage also may differ between laparoscopic and open LAR. According to these studies, the anastomotic level, number of linear staples, sex, smoking habits, alcohol intake, previous abdominal surgery, preoperative chemoradiotherapy, tumor location, stage, operative duration, blood loss volume, transfusion, and precompression before firing are reported risk factors for anastomotic leakage after LAR. In the present study, our analysis of potential risk factors suggests that the presence of underlying disease, the use of transanal hand-sewn anastomosis, and the use of closed drains may increase the risk for anastomotic leakage.

In some studies, intraoperative blood loss volume was a reported independent risk factor for anastomotic leakage [17-19, 21, 22]. In the present study, we found no significant association between blood loss volume as a continuous variable and anastomotic leakage. This finding suggests that anastomotic leakage did not occur directly because of bleeding and that intraoperative blood loss volume was likely to be a surrogate for surgical difficulty.

The duration of surgery is a reported risk factor in some studies [23-25]. Our study confirmed that patients with a longer surgical duration had a higher incidence of anastomotic leakage. Prolonged surgery may be caused by lower surgical skill or poor exposure of the surgical field secondary to pelvic stenosis or a large tumor. In addition, decreased blood perfusion caused by prolonged anesthesia may increase the risk of anastomotic leakage.

Previous studies have reported that diabetes mellitus is a risk factor for anastomotic leakage [26, 27], which our results confirmed (Table 3). Possible reasons for this increased risk include the following: insufficient blood supply to the anastomosis secondary to microcirculatory disorders, insufficient glycogen stores, and delayed tissue healing secondary to hyperglycemia. These results suggest that patients with type 2 diabetes mellitus require good blood glucose control before surgery to reduce the risk of anastomotic leakage post-LAR. However, other studies have found that diabetes was not a risk factor for anastomotic leakage [16, 28].

Sánchez-Guillén et al. reported the perioperative risk factors for anastomotic leakage and for 60-day morbidity and mortality after ileocolic anastomosis (stapled vs hand-sewn). The authors' multivariate analysis showed the following independent risk factors for major anastomotic leak: male sex ($P = 0.0140$, odds ratio [OR]: 2.9), arterial hypertension ($P = 0.0480$, OR: 2.29), and perioperative transfusion ($P < 0.0010$, OR: 2.4 per liter). The overall 60-day complication rate in that study was 27.3%. Male sex (31.3% complication rate vs 22.3% among female patients, $P = 0.0200$, OR: 1.7), diabetes ($P = 0.0300$, OR: 2.0), smoking habit ($P = 0.0400$, OR: 1.8), and perioperative transfusion ($P < 0.0010$, OR: 3.3 per liter) were independent risk factors for postoperative morbidity [29]. These results are consistent with our underlying disease results, which suggest that the presence of underlying disease is associated with anastomotic leakage.

Several studies have reported that tumor location and distance from the anal verge are risk factors for anastomotic leakage after LAR [13-17, 20]. Choi et al. reported that the anastomotic leakage rate was 10 times higher when the anastomotic region was located within 5 cm of the anal verge in a series of 156 patients who underwent LAR without double stapling [15]. It is hypothesized that tumor location and distance from the anal verge may reflect technical difficulty and affect anastomotic tension and blood supply. In multivariate analysis in the present study, there was a statistically significant difference in leakage occurrence between double-stapling and hand-sewn anastomosis. Therefore, we concluded that these were likely risk factors for anastomotic leakage.

Our results showed that the type of drain was related to anastomotic leakage after LAR. To our knowledge, this result has not been reported previously and is considered an important finding. An open drain can be used for effective long-term drainage, but the possibility of retrograde infection is a concern. In contrast, a closed drain is less likely to be associated with retrograde infection, but obstruction is a problem. Although some reports have described the risk of retrograde infection in patients with open drainage [30-32], none has reported the related frequency or any diagnostic criteria. In the present study, no retrograde infection occurred in patients with open drainage. A peritoneal defect is sometimes present within the pelvis after rectal resection. This loss of peritoneum decreases reabsorption of effusion and increases the risk of infection, predisposing to abscess formation. There is a strong possibility that these conditions lead to leakage.

Because efficient fluid drainage is important, we consider it necessary to carefully consider which type of drain to use in digestive surgery. Surprisingly, in the propensity-score analysis, patients with closed drainage had a 6.315 times higher risk of postoperative leakage than those with open drainage. This finding is impressive and important, and statistically meaningful.

The limitations of this study must be addressed. The major limitations are the single-institution, retrospective design and the small number of patients. In fact, the rate of anastomotic leakage in this study was slightly higher (21.7%) than that in other studies. This higher percentage may be attributed to the fact that many of the patients in this study had advanced disease. Moreover, many patients had Rb-positive lesions, which may have caused selection bias. Additionally, we excluded patients who received preoperative chemotherapy or chemoradiotherapy because of our department's treatment policy.

These limitations should be considered when evaluating the results of our study. A prospective study involving multiple institutions with a unified definition of anastomotic leakage and standardized procedures is needed. However, to our knowledge, no studies have collected and analyzed drainage data in patients undergoing lower rectal surgery; therefore, our findings are noteworthy.

Conclusion

Anastomotic leakage is a multifactorial complication after LAR. Patients' characteristics cannot be changed, but several techniques and devices can be used to avoid this complication. We demonstrated that in patients with anastomotic leakage after LAR, leakage frequency was higher in those with underlying disease, in those who underwent transanal hand-sewn anastomosis, and in those with closed drainage. Our results suggest that it is necessary to determine the need for a drain and to select the drainage method after comprehensive assessment of the surgical procedure and the patient's condition.

Declarations

Ethics approval and consent to participate

The Institutional Review Research Committee for Human Subjects at Kurume University Hospital approved the study (no. 18197). Written informed consent was obtained from each of the patients prior to enrollment in this study.

Consent for publication

Not applicable

Availability of data and materials

After publication of the primary findings, the de-identified and completely anonymized individual participant-level dataset will be posted on the UMIN-ICDR website (http://www.umin.ac.jp/icdr/index-j.html) so that it can be accessed by qualified researchers.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

TK designed the study; TK, SN, KM, TM, TO, TI, FF, and YA collected data; TM reviewed patients' histology; TK, SN, and KM analyzed the data, reviewed the charts, and interpreted the data; TK wrote the paper. All authors have read and approved the manuscript.

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Abbreviations

BMI: body mass index; LAR: low anterior resection; IPTW: inverse probability of treatment-weighted; HR: hazard ratio; CI: confidence interval; OR: odds ratio

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Tables

Table 1. Background Clinical Characteristics of Enrolled Patients

	(n=97)
Age (years : mean ± SD)	64.2± 10.76
Sex (male/female)	76 / 21
BD (positive / negative)	44 / 53
BMI (kg/m^{2}: mean ± SD)	22.6 ± 3.45
Blood loss (mls : mean ± SD)	316.0 ± 386.37
Operative duration (mins : mean ± SD)	363.0 ± 95.80
Anast (DST / HS)	59 / 38
Drain (open / close)	56 / 41
Alb (g/dl : mean ± SD)	3.93 ± 0.46
Drainage volume (mls : mean ± SD)	765.0 ± 451.36
LLD (+ / -)	15 / 82
Operation (CAA, ISR / LAR, uLAR)	38 / 59
Stage (I+II / III+IV)	58 / 39

BD: basal disease, BMI: body mass index, Anast: anastomosis,

DST: double-stapling technique, HS: hand-sewn, LLD: lateral lymph node dissection,

CAA: coloanal anastomosis, ISR: intersphincteric resection, uLAR: ultra-low anterior resection, Alb: albumin

Table 2. Background Clinical Characteristics of Patients with versus without Leakage

Leakage

	Positive (n=21)	Negative (n=76)	p-value
Age (years : mean ± SD)	65.81 ± 8.80	63.737 ± 11.2	0.4377
Sex (Male/Female)	17 / 4	59 / 17	1
BD (Positive / Negative)	13 / 8	31 / 45	0.1362
BMI ($kg/m^{2:}$ mean ± SD)	23.51 ± 2.40	22.38 ± 3.67	0.1853
Blood loss (mls: mean ± SD)	325.71 ± 378.3	313.89 ± 388.6	0.8863
OP time (mins: mean ± SD)	418.04 ± 89.7	348.01 ± 92.3	0.0026
Anast (DST / HS)	8 / 13	51 / 25	0.0227
Drain (Open / Close)	9 / 12	47 / 29	0.1395
preoperative Alb (g/dL: mean ± SD)	3.91 ± 0.42	3.94 ± 0.48	0.8531
Drainage volume (mls: mean ± SD)	688.95 ± 449.9	785.68 ± 452.3	0.3875
LLD (+ / -)	3 / 18	12 / 64	1
OP (CAA, ISR / LAR, uLAR)	13 / 8	25 / 51	0.0227
Stage (I+II / III+IV)	11 / 10	47 29	0.4601

BD: basal disease, BMI: body mass index, OP: operation, Anast: anastomosis, DST: double-stapling technique, HS: hand-sewn, LLD: lateral lymph node dissection, CAA: coloanal anastomosis, ISR: intersphincteric resection, uLAR: ultra-low anterior resection, Alb: albumin

Table 3. Univariate and Multivariate Analyses of Leakage in Patients with Low Anterior Resection

ctor		OR	95%CI	P value	OR	95%CI	P value
x	Male	1					
	Female	0.817	0.242-2.754	0.7439			
e /years		1.019	0.972-1.069	0.4343			
sal disease		2.359	0.874-6.364	0.0901	3.258	1.032-10.283	0.044
MI		1.099	0.955-1.265	0.1862			
od loss (mls)		1	0.999-1.001	0.8848			
eratiive duration (mins)		1.008	1.002-1.013	0.0051	1.007	1-1.013	0.0533
ast	DST	1			1		
	Hand sewn	3.521	1.289-9.617	0.0141	5.07	1.31-19.632	0.0188
ain	Open	1			1		
	Closed	2.161	0.811-5.76	0.1235	4.311	1.2-15.484	0.0251
eoperative Alb		0.905	0.321-2.558	0.8513			
scharge volume mls		1	0.998-1.001	0.3844			
D performed		0.889	0.226-3.494	0.8661			
age	I + II	1					
	III + IV	1.473	0.557-3.9	0.4352			
	CAA/ISR	1					
	LAR/uLAR	0.302	0.111-0.822	0.0191			

Anast: anastomosis, LLD: lateral lymph node dissection, BMI: body mass index,
DST: double-stapling technique, CAA: coloanal anastomosis, OP: operation
ISR: intersphincteric resection, uLAR: ultra-low anterior resection, Alb: albumin

Table 4. Propensity-Score Analysis

Method	Category	n	OR	95%CI		P value
Unadjusted	Open	97	1			
	Closed		2.161	0.811	5.76	0.1235
IPTW	Open	96	1			
	Closed		6.315	3.008	13.256	<0.0001
Matching	Open	32	1			
	Closed		5	0.492	50.831	0.1738

IPTW: inverse probability of treatment-weighted

Table 5. Average Drained Volume Analysis

Type of drain		
Group-O	56 cases (57.7%)	
Group-C	41 cases (42.3%)	
Average drained volume (mL)		
Group-O	954 ± 437.4	$p < 0.001$
Group-C	507 ± 328.0	

O: open drain, C: closed drain

Table 6. Relationship between Drain Type and Operative Procedure

Type of drain	Operation	
Group-O (56 cases)	CAA/ISR	28 cases (50.0%)
	LAR/u-LAR	28 cases (50.0%)
Group-C (41 cases)	CAA/ISR	10 cases (24.4%)
	LAR/u-LAR	31 cases (75.6%)

CAA: coloanal anastomosis, ISR: intersphincteric resection, uLAR: ultra-low anterior resection, O: open drain, C: closed drain

Figures

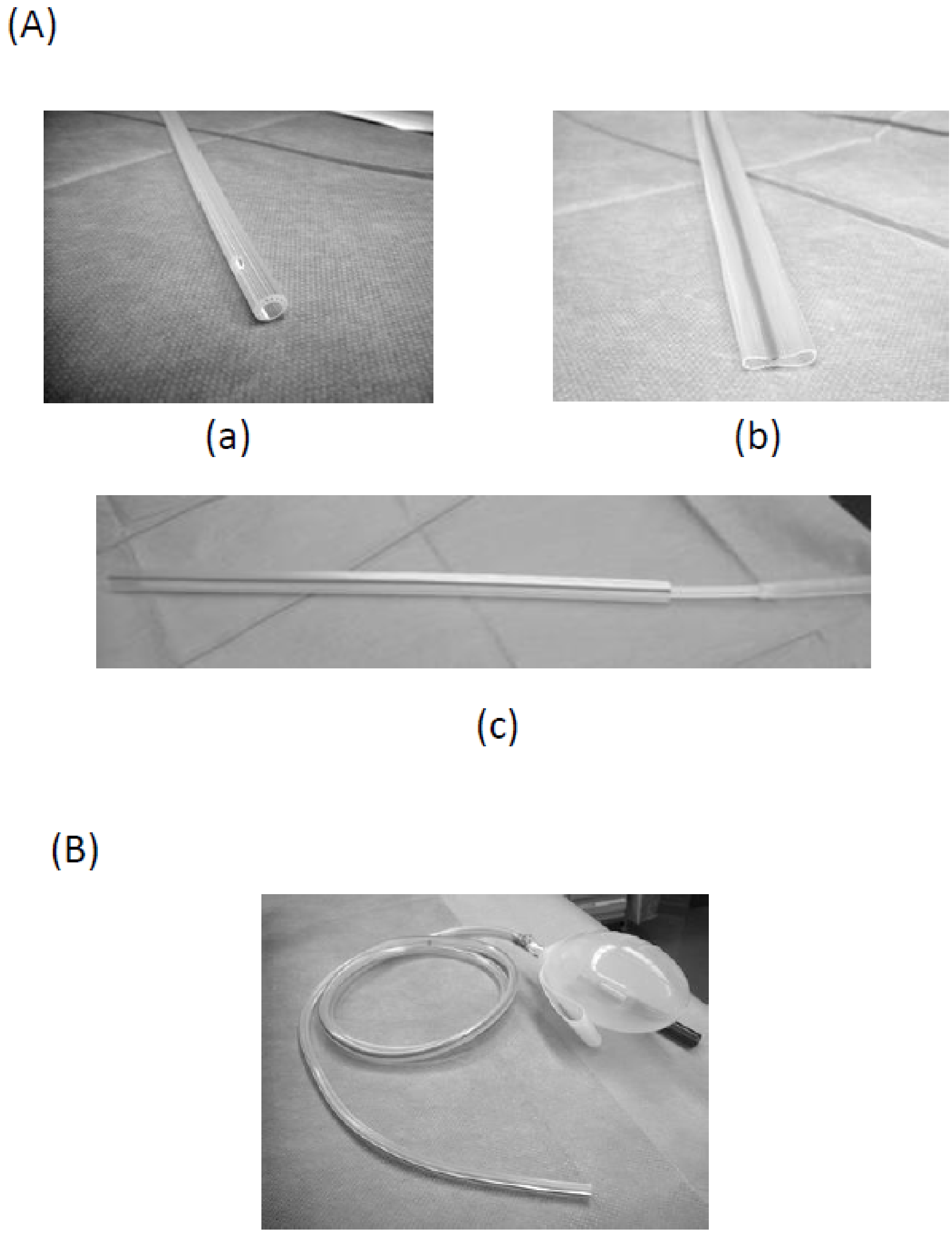

Figure 1

(A) Open drains. (a) Duple drain (6 Fr.); (b) Penrose drain (12 Fr.); (c) combining (a) and (b) into a single drain. (B) Closed drain. J-VAC drainage system (19 Fr.) (Johnson & Johnson, New Brunswick, NJ).