To Drain or Not to Drain Infraperitoneal Anastomosis After Rectal Excision for Cancer

The GRECCAR 5 Randomized Trial

Quentin Denost, MD, PhD,† Philippe Rouanet, MD, PhD,‡ Jean-Luc Faucheron, MD, PhD,§¶ Yves Panis, MD, PhD,|| Bernard Meunier, MD,** Eddy Cotte, MD, PhD,†† Guillaume Meurette, MD, PhD,‡‡ Sylvain Kirzin, MD, PhD,§§ Charles Sabbagh, MD, PhD,¶¶||||| Jèrôme Loriau, MD, PhD,*** Stèphane Benoist, MD, PhD,††† Christophe Mariette, MD, PhD,‡‡‡ Igor Sielezneff, MD, PhD,§§§ Bernard Lelong, MD,¶¶¶ François Mauvais, MD,|||||| Benoit Romain, MD,**** Marie-Line Barussaud, MD,†††† Christine Germain, MD,‡‡‡‡ Marie-Quitterie Picat, MD,‡‡‡‡§§§§¶¶¶¶ Eric Rullier, MD,*† and Christophe Laurent, MD, PhD*†, for the French Research Group of Rectal Cancer Surgery (GRECCAR)*

Objective: To assess the effect of pelvic drainage after rectal surgery for cancer.

Background: Pelvic sepsis is one of the major complications after rectal excision for rectal cancer. Although many studies have confirmed infectiveness of drainage after colectomy, there is still a controversy after rectal surgery.

Methods: This multicenter randomized trial with 2 parallel arms (drain vs no drain) was performed between 2011 and 2014. Primary endpoint was postoperative pelvic sepsis within 30 postoperative days, including anastomotic leakage, pelvic abscess, and peritonitis. Secondary endpoints were overall morbidity and mortality, rate of reoperation, length of hospital stay, and rate of stoma closure at 6 months.

Results: A total of 494 patients were randomized, 25 did not meet the criteria and 469 were analyzed: 236 with drain and 233 without. The anastomotic height was 3.5 ± 1.9 cm from the anal verge. The rate of pelvic sepsis was 17.1% (80/469) and was similar between drain and no drain: 16.1% versus 18.0% ($P = 0.58$). There was no difference of surgical morbidity (18.7% vs 25.3%; $P = 0.83$), rate of reoperation (16.6% vs 21.0%; $P = 0.22$), length of hospital stay (12.2 vs 12.2; $P = 0.99$) and rate of stoma closure (80.1% vs 77.3%; $P = 0.53$) between groups. Absence of colonic pouch was the only independent factor of pelvic sepsis (odds ratio = 1.757; 95% confidence interval 1.078–2.864; $P = 0.024$).

Conclusions: This randomized trial suggests that the use of a pelvic drain after rectal excision for rectal cancer did not confer any benefit to the patient.

Keywords: anastomotic leakage, pelvic drain, pelvic sepsis, rectal cancer

(*Ann Surg* 2016;xx:xxx–xxx)

From the *Colorectal Unit, Haut Lévêque Hospital, CHU Bordeaux, France; †University of Bordeaux, Bordeaux, France; ‡Surgical Oncology Department, Montpellier Cancer Institute (ICM), Val d'Aurelle, Montpellier, France; §Colorectal Unit, Department of Surgery, Michallon University Hospital, Grenoble, France; ¶University Grenoble Alpes, Grenoble, France; ||Department of Colorectal Surgery, Beaujon Hospital (AP-HP), Paris VII University, Clichy, France; **Department of Surgery, Pontchaillou University Hospital, Rennes, France; ††Department of Digestive Surgery, Hospital Center Lyon-Sud, University of Lyon, Lyon, France; ‡‡Department of Surgery, Hotel Dieu University Hospital, Nantes, France; §§Department of Surgery, Purpan University Hospital, Toulouse, France; ¶¶Department of Digestive and Oncological Surgery, Amiens Picardie University Hospital, Amiens, France; ||||Inserm Unit, Picardie Jules-Verne University, Amiens, France; ***Department of Digestive Surgery, Saint-Joseph Hospital, Paris, France; †††Department of Surgery, Bicêtre University Hospital (AP-HP), Le Kremlin-Bicêtre cedex, France; ‡‡‡Department of Digestive and Oncological Surgery, Claude Huriez University Hospital, UniversityLille, Lille, France; §§§Department of General and Digestive Surgery, University of Aix Marseille, Marseille, France; ¶¶¶Department of Digestive and Oncological Surgery, Paoli-Calmettes Institute, Marseille, France; ||||||Department of Digestive Surgery, Beauvais Hospital, Beauvais, France; ****Department of General and Digestive Surgery, Strasbourg University Hospital, Strasbourg, France; ††††Department of Digestive Surgery, University Hospital of Poitiers, Poitiers, France; ‡‡‡‡Medical Information Department, USMR, CHU de Bordeaux—Public health pole, Bordeaux, France; §§§§INSERM, ISPED, INSERM Center U897—Epidemiology-Biostatistic, Bordeaux, France; and ¶¶¶¶ISPED, INSERM U897 Center-Epidemiology-Biostatistic, University Bordeaux, Bordeaux, France.

Reprints: Eric Rullier, MD, Unité Colorectale, Service de Chirurgie Digestive, Hôpital Magellan, 33600 Pessac/Bordeaux, France.
E-mail: eric.rullier@chu-bordeaux.fr.

Disclosure: The authors report no conflicts of interest.

ISSN: 0003-4932/14/26105-0821
DOI: 10.1097/SLA.0000000000001991

During the last 2 decades, strategies for rectal cancer have completely changed including the introduction of total mesorectal excision (TME) and neoadjuvant chemoradiotherapy, which have led to a higher rate of sphincter-saving procedure.[1–3] Concurrently, concerns and awareness regarding anastomotic leakage and pelvic sepsis associated with TME have been reported[4,5] with a rate varying from 3% to 28%.[6] The occurrence of anastomotic leakage appears to be higher after TME than after colonic resection[7] and is associated with a high rate of mortality, reoperation, and definitive stoma formation.[8,9] These differences between rectal and colonic resection may explain different management of both anastomoses and postoperative drainage. In this way, many studies have assessed the interest of drainage after colorectal surgery and confirmed its infectiveness after colonic procedure, whereas, to date, the effect of pelvic drain in infraperitoneal anastomoses after rectal excision remains unclear and controversial.[9–13]

The rationale of using pelvic drainage after TME rests firstly on reducing the incidence of infraperitoneal anastomotic leakage and pelvic sepsis,[9] secondary on tracking the anastomotic failure to both detect early anastomotic leakage and decrease the needs of reoperation thanks to the ''so called'' driving effect of the drain,[9,10] and finally on avoiding potential contamination of postoperative pelvic fluid.[7,14,15] Even if the rationale of using prophylactic pelvic suction drain seems to be easy to understand, the level of evidence, which support this practice is low. Indeed, data that support the use of pelvic drain after TME are only retrospective,[10] and the 3 prospective

randomized trials performed had a small sample size with anastomoses both above and below the peritoneal reflection.[11–13] Regarding the lack of strong evidence, authors suggested that it is wise to establish drainage of the presacral space after TME.[9]

Some authors have, however, reported potential risks of drainage such as bowel perforation or obstruction, vessel injury, site of entrance for infection, and pain.[16] Furthermore, in accordance with the lack of evidence, the authors of the Cochrane review[7] recommended to perform a randomized trial focused on the pelvic drainage after anastomoses below the peritoneal reflection.

In this general setting, we aimed to assess the effect of prophylactic pelvic suction drain on postoperative pelvic sepsis after low anterior resection for cancer with low colorectal or coloanal anastomoses.

METHODS

Trial Design and Population Study

The GRECCAR 5 study is a multicenter, open-label, randomized, superiority phase III clinical trial conducted from January 2011 to July 2014 in France. Patients treated for rectal cancer and suitable for sphincter-saving resection with anastomoses below the peritoneal reflection were able to be randomized in 2 arms with a ratio (1:1): arm A, patients with pelvic suction drain and arm B, patients without pelvic drain. Details of eligibility criteria are given in Table 1. The randomization was performed by the surgeon the day before surgery after obtaining the patient's written informed consent. Each patient was followed during 6 months after surgery. The trial was approved by an ethics committee, conformed with good clinical practices and the declaration of Helsinki, and was supported by French government funding (ClincialTrials.gov no: NCT01269567). All patients signed an informed consent before participating in the study.

Preoperative Staging, Neoadjuvant, and Adjuvant Treatment

Preoperative evaluation included physical examination, colonoscopy with biopsy, pelvic magnetic resonance imaging, and abdominal computed tomography scan.

Following the French Guidelines,[17,18] patients with T3, T4, or N+ mid- or low rectal cancer received neoadjuvant treatment using 50 Gy in 25 fractions during 5 weeks with concomitant chemotherapy (5-fluorouracil) followed by surgery 6 weeks later.[19] Adjuvant chemotherapy (5-fluorouracil, capecitabine, and oxaliplatin) was given for patients with positive lymph nodes at the specimen (ypN+) and/or with R1 resection status within 6 to 8 weeks after surgery.

Surgery

Surgery was performed 6 weeks after radiotherapy. All patients had a preoperative bowel preparation. The operative technique was achieved by both open and laparoscopic procedures and included high ligation of the inferior mesenteric artery, left colonic mobilization from the lateral or medial approach, and extra facial excision of the mesorectum[1] with preservation of the hypogastric and pelvic plexuses.[20] In case of high rectal cancer, the rectum was transected 5 cm below the lower edge of the lesion.[21] The specimen was removed from a suprapubic 6 cm incision if the procedure was performed by laparoscopic approach and mechanical colorectal anastomosis was performed. In case of low rectal cancer, rectal transection was achieved transanally, the specimen was removed through the anal canal or through a suprapubic incision and a hand-sewn coloanal anastomosis was performed. A temporary stoma was used for anastomoses below 6 cm from the anal verge. At the end of the procedure a suction pelvic drain was placed behind the anastomosis in the presacral area for patients randomized in arm A.

Patients in all groups were treated according to the same postoperative protocol. Postoperative evaluation of C-reactive protein was systematically realized at days 3 and 6. A computed tomography scan was required when abscess or anastomotic leakage was clinically (fever, discharge of pus by the anus, or discharge of pus, gas, or stools by the vagina or the drain) or biologically (C-reactive protein >100 mg/L) suspected. The pelvic drain was removed when the output of the drain was clear and lower than 100 mL/24 h.

Endpoints

Primary endpoint was pelvic sepsis within 30 days after surgery, and defined as occurrence of an anastomotic leakage, pelvic abscess, or peritonitis.

Secondary endpoints were (1) postoperative morbidity defined by significant morbidity, grades III, IV, and V as recommended by Dindo et al[22]: grade I was any deviation from the normal postoperative course; grade II included pharmacological treatment; grade III was complications requiring surgical, endoscopic, or radiological intervention; grade IV included life-threatening complications requiring intensive care unit management; and grade V complications caused postoperative death, wound infection was also considered in postoperative morbidity even if classified in grade I; (2) rate of reoperation; (3) length of hospital stay; (4) rate of stoma closure at 6 months.

Sample Size

We aimed to compare the postoperative pelvic sepsis between the 2 arms, which occurred within 30 days after surgery. In

TABLE 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Rectal adenocarcinoma, histopathologically proved	Colonic cancer (>15 cm from anal verge)
Stage T1 T2 T3 Nx Mx	Abdominoperineal resection
With or without neoadjuvant treatment	Associated resection (prostate, seminal bladder, vagina…)
Stapler or manual infraperitoneal anastomosis	Simultaneous liver resection
With or without loop ileostomy	Total proctocolectomy
With bowel preparation	Emergency procedure
Open or laparoscopic approach	Infected rectal tumor
Age ≥18 years	Patient already included in another clinical trial
Information of the patient and signature of informed consent	Pregnant women
Affiliation to a regime of social insurance	Women currently nursing
	Persons deprived of freedom or under guardianship
	Persons under protection of justice (article L1122-2 du Code de la Santé Publique)
	Persons unable to comply with follow-up for geographic, social, or psychic reasons

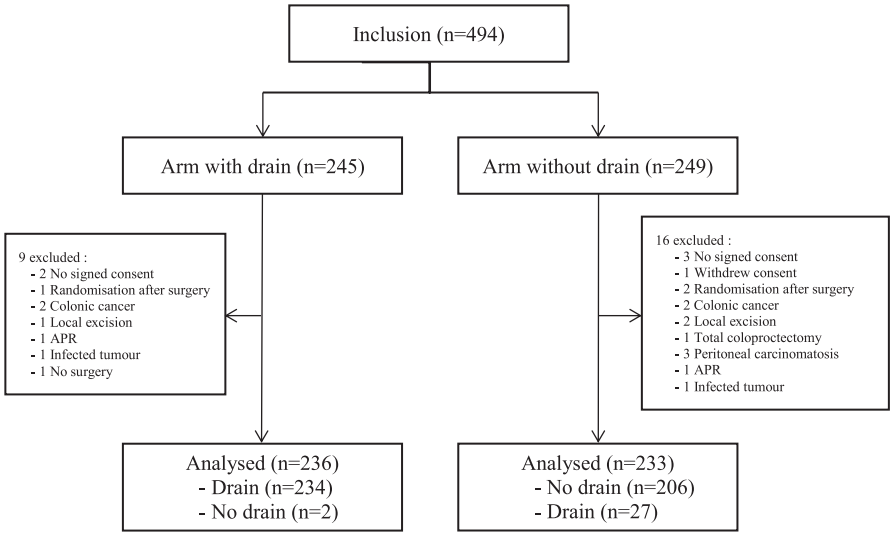

FIGURE 1. Flowchart. APR, abdominoperineal resection.

accordance with the literature,[8,9,23] a pelvic sepsis rate of 12% was expected in arm A. The sample size was calculated to show a difference of 10% regarding the primary endpoint between the 2 arms, considering this difference as clinically relevant. This trial was designed as a superiority trial, because the surgical practice of drainage was put into practice without evidence. In addition, controversies existed whether the drain might be beneficial or deleterious to patient. Subsequently, the hypothesis to test was whether the drain could prove to be superior to the absence of drain to further support this surgical practice. A noninferiority trial was refuted in this case, as noninferiority trials can be used provided that a comparator has already proven to be an efficacious strategy.[24] Superiority trials have been used in similar settings to change controversial clinical practice.[25]

An independent data and safety monitoring board periodically reviewed the efficacy and safety data. An interim efficacy analysis was performed during this trial. The levels of significance maintained an overall P value of 0.05 and were calculated according to the O'Brien-Fleming stopping boundaries. The final analysis used a P value of 0.0492. With a 2-sided 5% significance level and a power of 80%, an expected rate of 3% of patients for whom a pelvic drain would be used even if they were randomized in arm B (due to complications during the surgical procedure) and an expected rate of 2% of postoperative mortality, an initial sample size of 466 patients was needed (software Nquery Advisor v 6.0).

Statistical Analysis

All analyses were performed using SAS 9.13/SAS 9.3 (SAS Institute, Cary, NC). Qualitative variables were described as numbers (percentages) and quantitative variables as mean ± standard deviation. Differences between groups were assessed by χ^2 tests or Fisher exact tests when appropriate and by Student t test P value less than 0.05 was considered as statistically significant. Analyses were by intention to treat.

RESULTS

Population Study

During the trial, 494 patients were randomized in arm A (n = 245) and in arm B (n = 249). After exclusions of patients due to major protocol deviations, 469 patients were analyzed, 236 in arm A and 233 in arm B. Details of recruitment are given in Figure 1. Two patients allocated in arm A and 27 allocated in arm B did not receive the allocated surgical procedure with regards to using the pelvic drain. Causes of these changes were operative bleeding (n = 11), surgical dissection beyond the total mesorectal plane or technically difficult TME (n = 10), and misinterpretation of the randomization by the surgeon (n = 8). There were 316 men (67.4%) and the mean age of the population was 64.7 years. The lower edge of the tumor was 6.9 ± 3.4 cm from anal verge with 85% of tumors lower than 10 cm, that is, mid- and low rectal cancer. Three hundred sixty-one patients (77%) had advanced local rectal cancer (T3T4) and 69% had a preoperative treatment. Demographic characteristics are detailed in Table 2. Rectal excisions were performed through laparoscopic approach in 93.6% of cases, and conversion to laparotomy occurred in 8.9% of procedures, without difference between the 2 arms. The anastomotic height was 3.5 ± 1.9 cm from the anal verge and a defunctioning stoma was performed in 75% of cases. Details of surgical procedures are given in Table 2. Patient characteristics and surgical procedures were balanced between arms.

Primary Endpoint

Among 469 patients considered for analysis, 80 patients (17.1%) had a pelvic sepsis within 30 postoperative days, without any significant difference between arms A and B (16.1% vs 18.0%, P = 0.58). None of the components of the primary outcome differed between arms (Table 3). The rate of pelvic sepsis increased from 13.2% postoperatively during the length of hospital stay to 17.1% at 30 days after surgery. Causes and postoperative evolution of pelvic sepsis are detailed in Table 3.

Postoperatively, the time between rectal excision and the diagnosis of pelvis sepsis was 7.8 ± 5.4 days overall (9.0 ± 6.8 vs 6.7 ± 3.3, P = 0.10) (Fig. 2), whereas the pelvic drain was removed at 5.6 ± 3.7 days. Early (<5 days) versus late (≥5 days) pelvic drain removal did not affect significantly the risk of pelvic sepsis (11.6% vs 18.6%, P = 0.122).

Univariate analysis of predictive factors of pelvic sepsis is reported in Table 4. In multivariate analysis, absence of colonic pouch was the only independent factor of pelvic sepsis after rectal excision for cancer and infraperitoneal anastomosis (odds ratio = 1.757; 95% confidence interval 1.078–2.864; P = 0.024).

Secondary Endpoints

The postoperative mortality within 30 days after surgery was 1.1% (5/469). The overall postoperative morbidity was 47.9% and the significant surgical morbidity, that is, stage III–V of Dindo

TABLE 2. Clinical and Surgical Characteristics

	Drain (n = 236)		No Drain (n = 233)		
	n	%	n	%	*P*
Sex ratio	(M/F)	158/78	66.9/33.1	158/75 (67.8/32.2)	0.84
Age, yr, mean (±SD)	64.0	11.5	65.5	11.4	0.15
BMI, kg/m^2, mean (±SD)	25.6	4.7	25.8	4.2	0.57
ASA					0.60
1–2	189	80.1	182	78.1	
3–4	47	19.9	51	21.9	
Height of the tumor, cm, mean (±SD)					
From anal verge	6.9	3.3	6.9	3.5	0.83
From anal ring	3.7	3.1	3.9	3.4	0.52
Tumor location					0.77
High rectum (10–15 cm)	33	14.0	37	15.9	
Mid rectum (5–10 cm	108	45.8	100	42.9	
Low rectum (≤5 cm)	95	40.3	96	41.2	
Tumor size, cm, mean (±SD)	3.3	1.7	3.3	1.8	
Preoperative tumor stage					0.54
mrT1	11	4.7	15	6.4	
mrT2	40	16.9	42	18.0	
mrT3	174	73.7	170	73.0	
mrT4	11	4.7	6	2.6	
Preoperative nodal stage					0.07
mrN0	69	29.2	76	32.6	
mrN1	158	66.9	138	59.2	
Nx	9	3.8	19	8.2	
Preoperative metastatic status					0.28
M0	211	89.4	215	92.3	
M1	25	10.6	18	7.7	
Preoperative treatment	173	73.3	152	65.2	0.06
Surgical approach					0.97
Open	15	6.4	15	6.4	
Laparoscopy	221	93.6	218	93.6	
Conversion	22	10.0	17	7.8	0.43
Height of anastomosis	3.4	1.9	3.5	2.0	0.88
>6 cm from anal verge	17	7.3	19	8.3	0.71
≤6 cm from anal verge	215	92.7	211	91.7	
Type of anastomosis					0.91
Mechanical	128	54.2	124	53.2	
Handsewn	108	45.8	109	46.8	
Defunctioning stoma					0.47
Yes	180	76.3	171	73.4	
No	56	23.7	62	26.6	
Length of procedure, min					
Mean (±SD)	268.5	86.0	264.7	81.8	0.63

ASA indicates American society anesthesiologists score; BMI, body mass index; SD, standard deviation.

TABLE 3. Details of Pelvic Sepsis

	Drain (n = 236)		No Drain (n = 233)		
	N	%	n	%	*P*
During initial hospital admission*					
Anastomotic leakage	22	9.3	20	8.6	0.78
Pelvic abscess	17	7.2	27	11.6	0.10
Peritonitis	8	3.4	9	3.9	0.78
30 Days after surgery*					
Anastomotic leakage	35	14.8	35	15.1	0.94
Pelvic abscess	27	11.5	35	15.2	0.24
Peritonitis	8	3.4	10	4.3	0.60

*Patient could have more than 1 event.

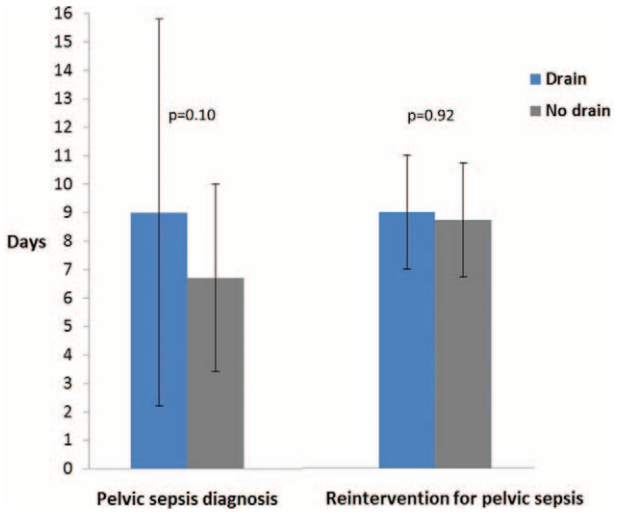

FIGURE 2. Time to diagnosis and reoperation for pelvic sepsis.

classification,[22] was 22% without significant difference between groups (18.7% vs 25.3%, $P = 0.83$). According to the Dindo classification, 15.6% of patients were grade III (73/469), 5.3% grade IV (25/469), and 1.1% grade V (5/469) without any difference between the 2 groups ($P = 0.14$). The rate of bowel obstruction within 30 days postoperatively was 19.9% in arm A versus 13.9% in arm B. This difference was not statistically different ($P = 0.08$), even if we can highlight a tendency in favor of the arm without drain. Medical morbidity within 30 days postoperatively included, without any difference between groups ($P = 0.96$), urinary morbidity, cardiac and respiratory insufficiency, and bacteremia.

The overall reoperation rate was 18.8%. This rate was not significantly different between arm A (16.6%) and arm B (21.0%) ($P = 0.22$). The rate of reoperation for pelvic sepsis was 11.1% (10.2% vs 12%; $P = 0.52$), and the time between rectal excision and the reoperation for pelvic sepsis was similar between groups (9.0 ± 3.3 vs 8.7 ± 4.9, $P = 0.92$) (Fig. 2). Details of reoperation for pelvic sepsis are reported in Table 5. All patients with pelvic sepsis, with or without reoperation, were managed with intravenous antibiotics.

The length of hospital stay was 12.2 ± 9.0 days and was similar in both group (12.2 vs 12.2, $P = 0.99$). The rate of stoma closure at 6 months was 78.8%, without significant difference between groups (80.1% vs 77.3%, $P = 0.53$).

DISCUSSION

The present study is the largest prospective randomized trial assessing the effect of pelvic drainage after rectal excision for cancer with infraperitoneal anastomoses. The main endpoint was the rate of pelvic sepsis within 30 days postoperatively including anastomotic leakage, pelvic abscess, and peritonitis. Results have shown that the presence of a pelvic drain after low anterior resection does not decrease both the risk of pelvic sepsis and the time to diagnosis and the risk of reoperation.

First of all, the rate of pelvic sepsis in our study appeared higher than expected, 17.3% instead of 12%. There are 2 main reasons, which could explain this dissimilarity. On the one hand, the present study was a prospective trial and the primary endpoint was the pelvic sepsis, which means that each causes of pelvic sepsis were carefully assessed without losing any data. Our hypothesis of a pelvic sepsis rate was 12% and rested on retrospective analysis with obviously a lot of bias and lost data.[8,9,23] Moreover, we considered the rate of pelvic sepsis up to 30 days after surgery and we showed that the rate of pelvic sepsis was higher at 30 days than postoperatively. This means that some cases were diagnosed after hospital discharge. It is easy to understand that we were able to highlight this difference due to the prospective feature of our study. On the other hand, our definition of pelvic sepsis included the anastomotic leakage, but the pelvic abscess and the peritonitis as well. This is a major difference compared with previous works, which did not consider pelvic abscess as an anastomotic failure[26] or which considered only anastomotic leakage with clinically apparent leak requiring a radiological or surgical reoperation.[6] This higher than expected rate of pelvic sepsis underline the strength of our randomized study to investigate the clinical effect of the drain on pelvic sepsis, as compared to previous retrospective observational studies.

The role of pelvic drainage in reducing the incidence of infraperitoneal anastomotic leakage and pelvic sepsis remained unclear until now. Indeed, even if a recent meta-analysis[10] concluded that pelvic drainage has a positive effect on anastomotic leakage occurrence, this conclusion was based on retrospective studies,[9,27] whereas prospective trials[11–13] did not show any difference between patients with or without pelvic drainage after rectal excision. Moreover, the high variability of anastomotic leakage from 4% to 23% in patients without pelvic drain reinforces the feeling of controversy regarding the effect of postoperative drain on pelvic sepsis.[9,11] The small sample size[11,13] and the inclusion of patients with anastomoses both above and below the peritoneal reflection[11,12] in the 3 previous randomized trials have affected the level of evidence of these studies. Therefore, surgical daily practice regarding pelvic drainage has been based on large retrospective studies[9] or national cohorts[8,23] in which authors recommended to use pelvic drain arguing its effect on reducing risk of anastomotic leakage. We have shown through the results of our prospective randomized trial including a large sample of patients with only infraperitoneal anastomoses that pelvic drainage does not decrease the risk of pelvic sepsis. This result confirms those of previous randomized trials[11–13] and, through it, should stop controversy regarding the use of pelvic drain after low anterior resection.

Another strong argument to defend the use of pelvic drain after low anterior resection is also to detect early anastomotic leakage and decrease the needs of reoperation thanks to its driving effect.[9,10] Indeed, in the retrospective assessment of predictive factors of symptomatic anastomotic leakage from the Dutch trial, authors concluded that the need for surgical reoperation after detection of anastomotic failure was significantly lower for patients with preexisting pelvic drainage compared with those without a drain (73.7% vs 96.7%, $P = 0.006$). Urbach et al[15] called this argument into question in a meta-analysis including 4 randomized trials and 414 patients with colorectal anastomoses, showing that among patients with anastomotic leakage, only 5% were diagnosed thanks to the fecaloid or purulent output of the drain. Nevertheless, authors did not carry out subgroup analysis of patients with anastomoses below the peritoneal reflection. This specific assessment has only been done by Jesus et al[7] who defined a subgroup of 191 patients with infraperitoneal anastomoses from their meta-analysis including 6 randomized controlled trial and 1140 patients. Authors concluded with regards to these 191 patients with anastomoses below the peritoneal reflection, 94 with drainage and 97 without drainage, that the rate of anastomotic leakage was not statistically different between patients with or without pelvic drain (11.7% vs 13.4%). We have shown as well that pelvic drainage does not decrease the rate of reoperation after low anterior resection. Our results confirm the trend previously reported[7,13,15] that pelvic drainage permits neither early pelvic sepsis diagnosis nor decreasing the need of reoperation. Moreover, the time

TABLE 4. Predictive Factors of Pelvic Sepsis (Univariate Analysis)

		Pelvic Sepsis				
	n	n	%	OR	95% CI	*P*
Randomization						0.580
Drain	236	38	16.1	0.87	0.54–1.41	
No drain	233	42	18.0	1.00		
Sex						0.036
Male	316	62	19.6	1.83	1.04–3.22	
Female	153	18	11.8	1.00		
Age	0.959					
≤65 yrs	245	42	17.1	1.01	0.63–1.64	
>65 yrs	224	38	17.0	1.00		
BMI						0.129
≤25.0 kg/m^2	218	31	14.2	1.00		
>25.0 kg/m^2	251	49	19.5	1.46	0.90–2.39	
American Society Anesthesiologists score						0.932
1–2	371	63	17.0	0.98	0.54–1.76	
3–4	98	17	17.3	1.00		
Height from anal verge						0.315
0–5 cm	191	27	14.1	1.00		
5–10 cm	208	38	18.3	1.36	0.79–2.33	
10–15 cm	70	15	21.4	1.66	0.82–3.34	
Tumoral stage						0.481
T1-T2	108	16	14.8	0.81	0.45–1.46	
T3-T4	361	64	17.7	1.00		
Synchronous metastases						0.777
Yes	43	8	18.6	1.12	0.50–2.52	
No	426	72	16.9	1.00		
Neoadjuvant treatment						0.496
Yes	325	58	17.8	1.21	0.71–2.06	
No	144	22	15.3	1.00		
Surgical approach						0.987
Open procedure	30	5	16.7	0.91	0.26–3.23	
Laparoscopy	400	68	17.0	0.94	0.40–2.21	
Conversion	39	7	17.9	1.00		
Surgery						0.268
Colorectal anastomosis	217	43	19.8	1.64	0.89–3.02	
Coloanal anastomosis	122	20	16.4	1.30	0.65–2.62	
Intersphincteric resection	130	17	13.1	1.00		
Height of anastomosis*						0.397
≤6 cm	426	71	16.7	1.00		
>6 cm	36	8	22.2	1.43	0.63–3.26	
Anastomosis						0.620
Stappled	252	45	17.9	1.13	0.70–1.84	
Hand sewn	217	35	16.1	1.00		
Colonic pouch						0.013
Yes	287	39	13.6	0.54	0.33–0.88	
No	182	41	22.5	1.00		
Protective stoma						0.170
Yes	351	55	15.7	0.69	0.41–1.17	
No	118	25	21.2	1.00		
Operative time*						0.438
≤260 min	240	44	18.3	1.21	0.75–1.97	
>260 min	224	35	15.6	1.00		

*Missing data.
ASA indicates American society anesthesiologists score; CI, confidence interval; OR, odds ratio.

to diagnose pelvic sepsis was 7.8 days, whereas drain was removed at 5.5 days postoperatively, highlighting the ineffectiveness of the drain for the diagnosis of pelvic sepsis. Reasons could be drain obstruction, drain displaced, drain at the opposite site of the anastomotic leak, or too early drain removal.

Finally, there is a theoretical risk for postoperative fluid to collect into the pelvis due to the large empty space remaining after TME, the absence of peritoneal surface in the pelvic fossa, the edema of pelvic tissue after preoperative radiotherapy, and the dependent position[7,14,15,28] leading to a potential contamination and pelvic abscess formation. There is, however, no evidence to support this theory. On the opposite side, some authors reported that the presence of a drain does not decrease pelvic fluid collection.[11–13] Our data do not support this theory as well with no difference between groups with regards to the pelvic abscess neither postoperatively nor at 30 days.

TABLE 5. Details of Reoperation for Pelvic Sepsis

	Drain (n = 236)		No Drain (n = 233)		
	n	%	n	%	*P*
Pelvic sepsis	38	16.1	42	18.0	0.58
Reoperation for pelvic sepsis	24	10.2	28	12.0	0.74
Drainage (surgical/radiological)	13		14		
Hartmann	5		8		
Defunctioning stoma	2		3		
Redo coloanal anastomosis	2		2		
Leakage stitching	2				
Endosponge*			1		

*Endoluminal vacuum-assisted closure therapy.

In conclusion, this prospective randomized trial failed to demonstrate the superiority of the pelvic drainage after low anterior resection for rectal cancer. Therefore, we recommend not using pelvic drain after rectal excision for cancer, except in case of operative bleeding or beyond TME surgery.

ACKNOWLEDGMENTS

The authors gratefully acknowledge Mrs Guillon Stephanie for her commitment in the management of data during the study period and Dr Doussaud Adelaïde for her support regarding the correction of the manuscript.

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