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Omentoplasty in the Prevention of Anastomotic Leakage After Colonic or Rectal Resection

A Prospective Randomized Study in 712 Patients

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Objective
To investigate the role of omentoplasty (OP) in the prevention of anastomotic leakage after colonic or rectal resection.

Summary Background Data
It has been proposed that OP—wrapping the omentum around the colonic or rectal anastomosis—reinforces intestinal sutures with the expectation of lowering the rate of anastomotic leakage. However, there are no prospective, randomized trials to date to prove this.

Methods
Between September 1989 and March 1994, a total of 705 patients (347 males and 358 females) with a mean age of 66 ± 15 years (range, 15–101) originating from 20 centers were randomized to undergo either OP (n = 341) or not (NO, n = 364) to reinforce the colonic anastomosis after colectomy. Patients had carcinoma, benign tumor, colonic Crohn's disease, diverticular disease of the sigmoid colon, or another affliction located anywhere from the right colon to and including the midrectum. Patients undergoing emergency surgery were not included. Random allotment took place once the resection and anastomosis had been performed, the surgeon had tested the anastomosis for airtightness, and the omental flap was deemed feasible. Patients were divided into four strata: ileo- or colocolonic anastomosis, supraperitoneal ileo- or colorectal anastomosis, infraperitoneal ileo- or colorectal anastomosis, and ileo- or coloanal anastomosis.

The primary end point was anastomotic leakage. Secondary end points included intra- and extraabdominal related morbidity and mortality. Severity of anastomotic leakage was based on the rate of repeat operations and related deaths.

Results

Both groups were comparable in terms of preoperative characteristics. Intraoperative findings were similar, except that there were significantly more septic operations and abdominal drainage performed in the NO group ($p < 0.05$ and $p < 0.01$, respectively). Thirty-five patients (4.9%) had postoperative anastomotic leakage, 16 in the OP group (4.7%) and 19 in the NO group (5.2%). There were 32 deaths (4.5%), 17 (4.9%) in the OP group and 15 (4.2%) in the NO group. Five patients with anastomotic leakage died (0.8%), 2 of whom had OP. There were 37 repeat operations (30%), 12 (6 in each group) for anastomotic leakage. Repeat operation was associated with fatal outcome in 14% of cases. The rate of these and the other intra- and extraabdominal complications did not differ significantly between the two groups.

Conclusion

OP to reinforce colorectal anastomosis decreases neither the rate nor the severity of anastomotic failure.

The colonic lumen contains 10^8 to 10^{10} aerobic and anaerobic germs per gram of feces, which is one of the reasons why postoperative infective complications occur more often after resection than in other elective abdominal surgical procedures: the incidence of these complications has been reported to range from 6%,[1] 20%,[2] 30%,[3] to 70%.[4] These complications are most often related to anastomotic leakage, the rate of which has been reported to range from 1% to 2%,[5,6] 3% to 5%,[7–9] and 10% to 25%,[10–12] depending on how rigorously it is sought. Anastomotic leakage is associated with 25% to 35% of deaths.[8] In case of carcinoma, anastomotic leakage is thought to be a risk factor for local recurrence and poor prognosis.[7]

Several methods have been proposed to decrease the rate and severity of infective complications and anastomotic leakage, including antibiotic prophylaxis,[2] colonic preparation with antiseptic enemas,[13] and fecal diversion protecting high-risk anastomoses.[14] Omentoplasty (OP) of colonic anastomoses has been proposed by several authors.[15–21] The rationale has been based on experimental studies,[15,18,21,22] clinical retrospectives,[19,23,24] or simple prospective studies.[25] We therefore undertook a multicenter prospective randomized trial to determine whether OP decreased the rate or the severity of anastomotic leakage after colonic or rectal resection.

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PATIENTS AND METHODS

Patients

Between September 1989 and March 1994 (4.5 years), 712 patients (360 females and 352 males) with a mean age of 66 ± 15 years (range, 15–101) and originating from 20 surgical centers (6 university, 11 teaching hospitals, and 3 private clinics) were eligible. Although all centers closed the study at the same date, the entry date varied from one center to another. The median number of patients enrolled in this study per year and per center was 35 (range, 6–137).

Patients had carcinoma, benign tumor, Crohn's disease, diverticular disease, or another affliction (relapsing chronic volvulus, angiodysplasia) located anywhere along the colon and the upper and the middle third of the rectum. Patients undergoing emergency surgery were not included.

This study was approved by the ethics committee of the coordinating center.

Methods

Surgery

To be eligible for this study, all patients were required to have mechanical preparation (laxatives) and antiseptic enemas and to undergo colonic resection followed by immediate anastomosis. Patients who could not be prepared correctly or did not undergo resection or anastomosis were not included. The type and choice of systemic

antibiotic prophylaxis administered at anesthesia induction were left to the discretion of each surgeon.

Anastomosis was performed either with absorbable or nonabsorbable, interrupted or continuous sutures, in one or two layers; with the GIA/TA stapling devices (Autosutures, Elancourt, France) for ileocolonic anastomoses[26]; or with a double-rowed circular stapling device for supra- or infraperitoneal colorectal[27,28] or ileorectal anastomoses.

Surgeons were asked to test for airtightness[29] by injecting air either: 1) directly into the colonic lumen via a needle inserted through the colonic wall between two supple intestinal clamps on either side of the anastomosis for ileo- or colocolonic anastomosis; or 2) through a Foley catheter inserted into the anus with the balloon inflated for colorectal or ileorectal anastomosis. If anastomotic leakage was detected, extra sutures were added until complete airtightness was obtained. For ileo- or coloanal anastomosis, testing for airtightness was impossible. When the omentum was mobilized, it was most often pedicled on the left gastroepiploic artery,[30] wrapped loosely around the anastomotic suture line, and tacked to the intestinal segments proximally and distally by individual sutures. Drainage of the abdominal cavity and use of fecal diversion were left to the choice of each surgeon.

Random Allotment

After the resection and anastomosis had been performed, the anastomosis had been tested for airtightness, and omentoplasty was deemed feasible, patients were allotted to one group or the other by revealing the phrase "omentoplasty" or "no omentoplasty" (NO), which had been hidden under the previously folded and stapled upper right-hand corner of a questionnaire.[31] Random assignment was determined according to random number tables[32] in four strata because of the known variation in the anastomotic leakage rate depending on the site of anastomosis.[10,11,33-37] The four categories were ileo- or colocolonic anastomosis; supraperitoneal ileo- or colorectal anastomosis; infraperitoneal ileo- or colorectal anastomosis; and ileo- or coloanal anastomosis. Random allotment was balanced every four patients within each strata and within each center.

End Points

The primary end point was the rate of postoperative anastomotic leakage diagnosed by the egress of fecal fluid through drains, by repeat operation or autopsy (performed routinely for all patients who died during their hospital stay), or by sodium diatrizoate enema performed routinely near day 7 for asymptomatic patients. Anastomotic leakage was defined as all images other than a perfectly regular and uniform caliber at the level of the anastomosis.[27] Secondary end points included intra- and extraabdominal related morbidity and mortality. The severity of anastomotic leakage was based on the number of repeat operations and related deaths. The postoperative period was defined as the hospital stay, irrespective of duration, and the 30 days after patient discharge. All patients were recalled at that date because late infective complications are known to occur occasionally after patient discharge.[38] Factors studied related to leakage included type of disease, site of anastomosis, septic factors, use of fecal diversion, testing for airtightness, and type of leakage (clinical or radiologic alone).

Table 1. COMPARABILITY OF GROUPS: PREOPERATIVE CHARACTERISTICS

	Omentoplasty (341)	No Omentoplasty (364)	Total (705)
Sex ratio (M/F)	0.86 (158/183)	1.08 (189/175)	0.96 (347/358)
Age (yr) (mean ± 1 SD)	66 ± 15	66 ± 15	66 ± 15
Range	20–98	15–101	15–101
Weight loss*	98	107	205
Obesity > 20% theoretical weight	82	84	166
Cirrhosis	7	7	14
Ascites	16	17	33
Carcinomatosis	11	10	21
Cirrhosis	5	7	12
Corticosteroids, radiation, chemotherapy	16	21	37
Respiratory failure	29	27	56
Cardiovascular disorders	20	22	42

* Loss of more than 10% of usual weight.

Number of Patients Required

According to the pragmatic method,[32,39] in order to decrease the rate of anastomotic leakage from 8% to 4% with a gamma risk (that of choosing the worse of two treatments) of 1%, 340 patients were required in each group, or 680 patients in all.[32]

Statistical Analysis

Groups were compared using the chi square test for categorical variables, Student's t test for continuous variables, and the Mann-Whitney U test for nonparametric values.

RESULTS

Seven patients were withdrawn from analysis after random allotment. Five of them were incorrectly categorized as to their strata (different anastomotic site); in one case,

Table 2. COMPARABILITY OF GROUPS: INTRAOPERATIVE FACTORS POSSIBLY PROMOTING LEAKAGE

	Omentoplasty (341)		No Omentoplasty (364)		Total (705)		
	Number of Leaks	Number of Patients	Number of Leaks	Number of Patients	Number of Leaks	Number of Patients	%
Total number of anastomotic leaks	16	341	19	364	35	705	4.9
Site of anastomosis							
Colonic	0	146	2	148	2	294	0.7*
Supraperitoneal rectum	11	140	9	164	20	304	6.6*
Infraperitoneal rectum	5	46	5	49	10	95	10.5*
Anus	0	5	3	7	3	12	25.0*
Disease							
Carcinoma	9	228	10	237	19	465	4.0†
Curative resection	8	201	6	182	14	383	3.7
Palliative resection	1	27	4	55	5	82	6.3
Sigmoid diverticular disease†	6	60	9	71	15	131	11.4†
Miscellaneous	1	53	0	56	1	109	0.9
Septic factors‡							
No	9	272	14	264§	23	536	4.3
Yes	7	69	5	100	12	169	7.1
Drainage							
With	6	134	9	180¶	15	314	4.8
Without	10	207	10	184	20	391	5.1
Anastomosis							
Manual	14	205	10	206	24	411	5.9
Mechanical	2	136	9	158	11	294	3.7
Diverting colostomy							
With	5	25	5	30	10	55	18.2†
Without	11	316	14	334	25	650	3.8†
Testing for air-tightness							
No air leak	11	245	11	272	22	517	4.2
Air leak	5	18	4	24	9	42	21.4‖
Not performed	0	78	4	68	4	146	2.7‖

* $p < 0.001$.
† $p < 0.0003$.
‡ Abscess, infected tumor, intraoperative fecal soiling.
§ $p < 0.05$.
‖ $p < 0.0005$.
¶ $p < 0.01$.

resection was not followed by anastomosis; and in the remaining case, the omentum was found to be retracted and was unusable. Final analysis included 705 patients (341 OP, 364 NO).

Comparability of the Two Groups

As shown in Table 1, preoperative characteristics of the two groups of patients were comparable, except that there were more females in the OP group and more males in the NO group, with a nearly significant difference ($p < 0.10$). Intraoperative findings (Table 2) were similar, except that septic factors (abscess, infected tumor, and intraoperative fecal soiling) and abdominal drainage were more frequent in the NO group ($p < 0.05$ and $p < 0.01$, respectively). Carcinoma was the most frequently encountered disease (64%) and was resected with curative intent in 82% of cases.

Anastomotic Leakage

Thirty-five patients (4.9%) had postoperative anastomotic leakage (Table 3), 5.1% in the OP group and 4.7% in the NO group. The diagnosis of anastomotic leakage was made clinically in 11 cases; in the remaining 24 cases, leakage was detected by routine water-soluble (sodium diatrizoate) radiograms alone. Even after adjusting for intraoperative septic factors and drainage (statistically different in both groups; see Table 2),[40] the rate of anastomotic leakage remained similar between the two groups.

Table 3. RESULTS

	Omentoplasty (341)	No Omentoplasty (364)	Total (705)
Early abdominal complications			
Wound abscess	8	12	20
Wound disruption	1	3	4
Anastomotic leakage	16	19	35
Clinical	4	7	11
Radiological alone	12	12	24
Generalized or localized peritonitis	14	16	30
Deep hematoma or hemoperitoneum	2	0	2
Repeat operation	16	21	37
Abdominal complications at 1 mo			
Wound abscess	5	4	9
Ventral hernia	5	2	7
Total number of patients with one or more early complications and/or after 1 mo	32	30	62
Extra-abdominal complications	90	109	199
Septic	36	51	87
Nonseptic	44	47	91
Blood-borne infection	10	11	21
Deaths	17	15	32
Without intra-abdominal complications	8	12	20
With intra-abdominal complications	9	3	12
With anastomotic leakage	2	3	5

Other Complications

The other intra- and extraabdominal complications did not differ significantly between the two groups (see Table 3). The rate of patients with one or more abdominal complications was 9% in the OP group and 8% in the NO group. Twenty-six percent of patients in the OP group and 30% in the NO group had extraabdominal complications. Abdominal complications occurred in 2.3% of patients within 1 month after hospital discharge.

Deaths

There were 32 deaths (4.5%), 17 (4.9%) in the OP group and 15 (4.2%) in the NO group. In 12 patients (17% of deaths), the cause of death was intraabdominal, including 5 patients (0.8%) with anastomotic leakage (2 in the OP group, 3 in the NO group), intraabdominal bleeding (subcapsular hematoma of the liver and hemorrhage related to anticoagulant therapy for pulmonary embolism in 1 case each), hepatic failure (2 patients with hepatic metastases and 1 with cirrhosis), acute pancreatitis (1 patient); the remaining patient died of peritonitis without overt anastomotic leakage. This last patient sustained massive intraoperative soiling during resection with OP for repeated subacute obstruction of the right colon due to malrotation. In the 20 other patients, the cause of death was extraabdominal: 7 respiratory, 7 cardiac, 4 infective (3 cases of bloodborne infection and 1 case of pyelonephritis), and 2 neurologic causes.

Risk Factors Associated With Anastomotic Leakage

Independently of whether OP was performed or not, the risk of anastomotic leakage was significantly associated with diverticular disease ($p < 0.001$); the distal site of anastomosis (rectum or anus) ($p < 0.01$); performance of fecal diversion ($p < 0.0003$); and absence of airtightness ($p < 0.0005$; Table 4). Of the 42 patients who were not airtight and had extra sutures added, 21% sustained definitive postoperative anastomotic leakages, 12% underwent repeat operations, and 2.4% died. In contrast, of the 517 patients who were airtight, 4.3% sustained postoperative leakage, 1% underwent repeat operations, and 0.6% died.

Severity of Anastomotic Leakage

Sixteen percent of deaths were associated with anastomotic leakage, and 14% of patients with anastomotic leakage died (see Table 4). Anastomotic leakage was associated with 30% of repeat operations; of 37 reoperations, 12 (30%) were for anastomotic leakage (6 in each group) (see Tables 3 and 4). There were 25 repeat operations without leakage (10 for local or generalized peritonitis, 6 for hemorrhage, 5 for wound disruption, 3 for obstruction, and 1 for postoperative acute cholecystitis), 11 in the OP group and 14 in the NO group. Patients with fecal diversion had significantly more leaks ($p < 0.0065$), more repeat operations ($p < 0.02$), and a higher rate of death ($p < 0.0003$).

DISCUSSION

Performing OP to protect anastomosis after colonic or rectal resection decreased neither the rate nor the severity of anastomotic leakage. Our rate of anastomotic leakage (4.9%) was close to that found by a survey of the literature ranging from 3% in 980 patients[7] to 4.5% in 1703 patients[8] and in 533 patients.[9] However, rates have been reported to range from 1% in 280 patients[5] and 2% in 921 patients[6] to 9% in 2057 patients.[10] These differences have varied with time and according to the rigor with which the diagnosis of leakage was sought. When clinical leakage only was taken into consideration, the rate was low.[5,6,9] If both clinical and radiologic leakage were tabulated, the rate averaged 3% to 4.5%.[7,8,10–12] In our study, the diagnosis of anastomotic leakage was clinical in one third of cases and radiologic alone in the other two thirds. These results differ from two other series in which the diagnosis was clinical and radiologic alone in 14 and 13

Table 4. SEVERITY OF LEAKAGES

	Number of Patients (705)	Number of Leakages (35)	Number of Repeat Operations (12)	Number of Deaths (5)
Disease				
Carcinoma	465	19	7	2
Sigmoid diverticular disease	131	15	4	2
Miscellaneous	109	1	1	1
Site of anastomosis				
Colonic	294	2	2	1
Proximal rectal	304	20	8	3
Distal rectal	95	10	2	1
Anal	12	3	0	0
Septic factors				
Yes	536	12	5	3
No	169	23	7	2
Diverting colostomy				
Yes	55	10	4	4
No	650	25	8	1
Testing for air-tightness				
Air-tight	517	22*	5	3
Not air-tight	42	9*	5	1
Not performed	146	4	2	1
Type of leakage				
Clinical	705	11	10	4*
Radiological only	705	24	2	1*

* $p = 0.0004$.

of 135 patients[34] and in 6 and 3 of 114 patients, respectively.[37] The difference in the leakage rate could very well be caused by the absence of an accurate definition of radiologic leakage in these series,[34,37] as compared with our definition.[27]

The technique of omental mobilization and wrapping of colorectal anastomoses has been described,[17,20] but neither of these authors reported their clinical experience. Lanter and Mason[19] reported 30 patients in whom low colorectal anastomoses were completely wrapped with omentum. There were no anastomotic leaks, but the technique of research and the definition of leaks were not specified. On the other hand, Smith et al.[25] reported 4 leaks in 26 patients with low colorectal anastomosis (15%), a rate three times higher than in our series. OP, however, was incomplete, covering only the posterior and lateral right aspects of the anastomosis. Leakage was sought by routine enema between the 10th and 14th postoperative days.

As found by others,[8,10,11,34,37,41] the anastomotic leakage rate increased as the site of anastomosis became more distal (see Table 4). Also, the rate of postoperative leakage in our study was significantly higher in diverticular disease than in other afflictions, especially in carcinoma (see Table 4), as already mentioned by others.[36,41,42] One reason for this might be the presence of residual local sepsis with microabscess formation, even in patients operated on several weeks after their acute episode.[41]

Intraoperative air leakage detected during testing for airtightness was associated with a high predictive value for postoperative anastomotic leakage, even when extra sutures were added (see Table 4). In our series, 21% of anastomotic leakages developed despite additional sutures in 42 patients who tested positive for leakage (see Table 4). This is close to the 20%[29] and 17%[35] anastomotic leakage rates described after adding extra sutures. However, Dixon et al.[42] did not observe any anastomotic leakages after positive testing in five cases, but three patients underwent fecal diversion. Our finding of increased anastomotic leakage after testing positive for airtightness, despite added sutures and independently of the anastomotic site,[29,37] should lead the surgeon to consider protecting it with proximal fecal diversion when possible, in addition to adding extra sutures or redoing the anastomosis.

Postoperative mortality was 4.5% in our series, close to that of Schrock et al[8] (4.2%). Smaller series have reported lower rates (3.5%,[37] 3%,[42] and 2%[5]), probably because selection was obviously restricted in monocenter studies as compared with multicenter trials.[32] There were significantly more septic factors and more abdominal drainages (see Table 2) performed in NO patients as compared with OP patients. However, because infective complications

and deaths were not more frequent, OP of the anastomosis probably did not improve the results.

To the best of our knowledge, indication for repeat operations has not been used to evaluate the severity of anastomotic leakage. In our study, 30% of repeat operations were caused by anastomotic leakage, whereas 30% of anastomotic leakages required repeat operations. In the literature, repeat operations were performed for 1 of 12,[36] 4 of 12,[43] and 13 of 17[33] leaks in the colon and 6 of 6 leaks in the lower rectum.[39] These differences are probably due to the way the diagnosis of leakage was sought (clinical or radiologic alone).

In our series, the overall rate of leakage-related deaths was 0.8%, close to the 0%,[5] 0.5%,[42] and 0.9%[8,37] rates found in the literature. Anastomotic leakage was responsible for 16% of the deaths, and 14% of patients with anastomotic leakages died. Death rates of 37%, 30%, 27%, and 25% associated with anastomotic leakage, respectively, and 33%, 31%, 28%, and 12% of patients, respectively, with leakage who died have been reported.[8,10,37,44] Differences in the severity of leakage may be due to whether fecal diversion is performed or not, as well as the method of diagnosis and treatment of patent anastomotic leakage.

Use of OP did not decrease the need for fecal diversion (see Table 4). Patients who underwent fecal diversion had 4 times as many anastomotic leakages ($p < 0.0005$), but these leakages were not statistically more severe (see Table 4). This is in accordance with the report by Fielding et al.,[10] who found that fecal diversion was associated with more anastomotic leakage, but all patients were high-risk. Fecal diversion *per se* did not prevent leakage, but this procedure was performed in patients who had the greatest risks of leakage, according to the surgeon's opinion.

As shown in this study, OP on colonic anastomosis does not provide any real advantages; on the contrary, it has been reported to be associated with potential risks, such as infection secondary to necrosis of the pedicled graft[45] and late intestinal obstruction[46,47] (neither of which were seen in our study). Moreover, when colectomy is performed for carcinoma, patients with OP are theoretically exposed to two further risks, including radiation necrosis[23] and local recurrence (described recently in the rat).[48]

In this era of laparoscopic colonic resection, where the rate of leakage might be high,[48] it is important to know that in the large population studied here, OP on the anastomosis is not effective and, because of its potential hazards, should not be used. This does not mean, however, that OP protection might not be useful for other indications, such as filling the pelvic cavity after abdominoperineal amputation.[23,25]

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