ORIGINAL ARTICLE

Cost-effectiveness of Defunctioning Stomas in Low Anterior Resections for Rectal Cancer

A Call for Benchmarking

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Hypothesis: Anastomotic leakage is the most important cost driver in patients who undergo low anterior resection (LAR) for rectal cancer. Creating defunctioning stomas to protect colorectal anastomoses may also have a major effect on the overall costs. Unselected creation of defunctioning stomas in most of these patients may be associated with higher overall costs compared with a program that has a low rate of defunctioning stomas and an acceptable anastomotic leakage rate.

Design: Cost-effectiveness analysis.

Setting: Secondary referral center.

Patients: Performing a cost analysis from the viewpoint of a hospital provider, we reviewed data of 70 consecutive patients who underwent LARs with (n=19) or without (n=51) a defunctioning colostomy. A scenario analysis was performed using data derived from the medical literature to assess a plausible range of leakage and stoma rates.

Main Outcome Measure: Costs per treatment option and incremental cost-effectiveness ratio according to various treatment scenarios.

Results: Performing an LAR without a stoma and no anastomotic leakage is associated with significantly lowest costs (€8.400; $P<.001$) compared with patients with a stoma (€13.985) and patients with anastomotic leakage (€42.250). The most important cost drivers were anastomotic leakages and defunctioning stomas. A leakage rate of 16.5% in patients without a stoma would be necessary to balance the overall costs of patients with stomas. The incremental cost-effectiveness ratio would be €158.705 and €60.915 per leak, respectively, avoided in patients with defunctioning stomas assuming a leakage rate lower than 3% and 6%, respectively, in patients who did not undergo a colostomy. A 1-way sensitivity analysis revealed that duration and costs of intensive care unit care were the only factors that may considerably alter our results.

Conclusions: A suggested benchmark for an LAR should be a rate of 10% or less for defunctioning stomas and anastomatic leaks; that would limit the overall costs to €12 000 per patient treated. Against the background of a lack of universally valid criteria for the creation of defunctioning stomas, our aim should be to reduce the rate of defunctioning stomas because of their major effect on the overall costs especially in programs with a lower leakage rate. Higher leakage rates despite higher stoma rates depend more on the skill of the surgeon than on the characteristics of the patient and higher leakage should lead to a change in surgical technique strategy.

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PRESERVATION OF continence has become a major objective in the surgical treatment of rectal cancer owing to better surgical techniques and new devices such as the circular endoscopic stapler (CEEA circular stapler; Tyco, Norwalk, Conn). Nevertheless, there is no common agreement in constructing defunctioning stomas to preserve the integrity of an anastomosis after low anterior resections (LARs).

See Invited Critique at end of article

On the one hand, risk management mandates the avoidance of complications caused by anastomotic disruption; on the other hand, constructing stomas in every patient after an LAR is costly as well as associated with the risk of additional morbidity.[1] Defunctioning stomas are used in up to 73% of patients with rectal cancer.[2-4] However, studies have been published that tried to reduce the rate of stomas resulting in a dehiscence rate of up to 32%.[5]

Our aim was to generate cost-effectiveness data for constructing an LAR with or without a defunctioning stoma. Some patients have a considerably higher

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risk for anastomotic leakage and, therefore, a stoma cannot be avoided. But there is another group of patients in whom the rate of stomas can be attributed to the skill of the individual surgeon rather than to the characteristics of the patient. Therefore, clear criteria are mandatory. It is also an objective to reduce defunctioning stomas by defining an acceptable rate of anastomotic complications in terms of cost-effectiveness and quality control. A range of benefits using a 1-way sensitivity analysis should increase the adaptability of the study to other institutions and other countries.

METHODS

Along with colleagues, I have previously published our treatment results from January 1, 1996, to December 31, 1998, in a consecutive series of patients with rectal cancer. Clinical data of 70 patients who underwent LARs were used in the present study for cost-effectiveness analysis.[6] Nineteen of these patients had a defunctioning stoma created that in every case was constructed as a transverse stoma in the epigastric region on the right side. Seven patients had defunctioning stomas created after coloanal anastomoses. All anastomoses in the present series were constructed as straight anastomoses. Patients with defunctioning stomas (n=19) were compared with patients without stomas (n=51) when performing a cost analysis. Three patients without stomas who did not receive preoperative radiotherapy had more proximal tumors and experienced clinical anastomotic leakage. All of these patients needed a Hartmann operation. Their data served as the basis for the cost analysis in patients with anastomotic dehiscences. There were 48 male and 22 female patients all treated with an LAR performing a total mesorectal excision in tumors of the lower and middle third of the rectum.

Tumor stages and location according to their distance from the anal verge are listed in **Table 1** and **Table 2**. A tumor in the distal third was defined by a distance of up to 8 cm from the anal verge, a middle third tumor was located 9 to 12 cm from the anal verge, and a proximal third tumor was located 13 to 16 cm from the anal verge. The patients in both groups were evenly distributed in terms of comorbidity risk (Table 1). Comorbidity was defined for the various organ systems as follows: (1) diabetes mellitus: insulin dependency; (2) cardiovascular: New York Heart Association classes III and IV ; (3) lung: chronic restrictive, obstructive, or vascular disease with chronic hypoxia, hypercapnia, or pulmonary hypertension; (4) kidney: hemodialysis; (5) liver: cirrhosis or portal hypertension; and (6) coagulation: thrombocyte count less than 50×10^9/L. Table 1 also gives the distribution of known risk factors for anastomotic leakage between both groups, but only a significantly higher proportion of tumors in the distal third of the rectum ($P<.001$) was found in the group of patients with stomas. Other known risk factors such as preoperative radiotherapy, age, male sex, and obesity did not significantly differ between the groups.

Five wound infections were recorded as stoma-related complications. Two of the 51 patients without stomas had pneumonia; 1 patient had a urinary tract infection. Overall, 2 patients died after undergoing LARs. One patient with a stoma had hepatic failure after undergoing an LAR, whereas 1 patient died after anastomotic dehiscence due to multiple organ dysfunction syndrome. According to the treatment policy of our department, all stomas were closed approximately 3 months after the initial operation.

Direct patient care costs were accounted to a disease-specific group of patients (those who underwent major alimentary tract surgery) that generated these costs for capital resources such as laboratory resources, diagnostic imaging, endoscopy, supplies, drugs, operating room costs, and costs of devices used during the operation. A mean of these costs was calculated per day of hospital and intensive care unit care as well as operation time for calculation of cost-effectiveness data. Discernible quantities of resources were not considered in detail as they are common to both groups and would not affect choice between the given programs. Moreover, these discernible resources are unlikely to make any difference to the study results. With regard to mean per diem costs of hospital care, costs of medications (€1.50), laboratory examinations (€8.90), and radiological examinations (€12.90) together only represent 10.1% of the overall per diem costs.

Table 1. Clinical Data of Patients With LAR for Rectal Cancer

Location*	UICC Stage	No. (%) of Patients With LAR and Stoma	No. (%) of Patients With LAR and No Stoma	P Value
Proximal third	I	0	11	
(n = 23)	II	0	5	
	III	0	4	
	IV	0	3	
	Overall†	0	**23** (45.1)	.001
Middle third	I	1	11	
(n = 23)	II	1	1	
	III	3	3	
	IV	0	3	
	Overall	**5** (26.3)	**18** (35.3)	NA*
Distal third	I	4	2	
(n = 24)	II	5	5	
	III	5	2	
	IV	0	1	
	Overall	**14** (73.7)	**10** (19.6)	<.001

Abbreviations: LAR, low anterior resection; NA, not applicable; UICC, Union Internationale Contre el Cancer.

*Location of tumors according to tumor stages and type of treatments.

†There was no statistically significant difference, but the power of the test was $\alpha<.80$.

Table 2. Comorbidity and Risk Factors of Patients With LAR for Rectal Cancer

Variable	No. (%) of Patients: With LAR and Stoma	No. (%) of Patients: With LAR and No Stoma	P Value
Comorbidity			
Diabetes mellitus	2 (10.5)	7 (13.7)	.99
Cardiovascular	3 (15.8)	10 (19.6)	.99
Lung	3 (15.8)	3 (5.9)	.33
Kidney	0	1 (2.0)	.99
Liver	3 (15.8)	2 (3.9)	.12
Coagulant therapy	1 (5.3)	0	.99
Risk factors			
Radiotherapy	6 (31.6)	8 (15.7)	.18
Male sex	15 (79.0)	33 (64.7)	NA*
Tumor location ≤8 cm	14 (73.7)	10 (19.6)	.001
BMI ≥35	3 (15.8)	1 (2.0)	.06

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by the square of height in meters); LAR, low anterior resection; NA, not applicable.

*There was no statistically significant difference, but the power of the test was $\alpha<.80$.

Table 3. Raw Data and Costs After LAR According to Groups of Treatment*

Raw Data	Patients Who Had LAR Without Stoma (n = 48)	Patients Who Had LAR With Leakage (n = 3)	Patients Who Had LAR With Stoma (n = 19)	*P* Value†
Age, y	69.3 (1.6)	76.7 (3.8)	65.4 (1.9)	NA‡
Distance to anal verge, cm	11.6 (0.5)	13.3 (1.7)	7.0 (0.6)	<.001
Duration of initial stay, d§	17.5 (0.7)	45.3 (8.3)	18.0 (1.0)	.011
Duration of ICU care, d	0.3 (0.2)	16.7 (5.2)	1.1 (0.8)	<.001
Duration of 2nd hospitalization, d	0	13.1 (2.8)	11.1 (0.9)	.43
Overall duration of operations, min	180.4 (9.7)	326.6 (30.2)	268.1 (18.1)	<.001
Costs, €	8400	42 250	13 985	<.001
Mean costs per day of care	230			
Mean costs per day of ICU care	1526			
Mean costs per operating minute	22			

Abbreviations: ICU, intensive care unit; LAR, low anterior resection; NA, not applicable.
*Data are given as mean (SD) unless otherwise indicated.
†One-way analysis of variance for comparison of the 3 groups or Mann-Whitney test for 2 groups.
‡Statistical significance was $P = .13$, but the power analysis revealed $\alpha = .05$ to .22, which was below the desired power of .80.
§The duration of ICU care is included.

Similarly for intensive care unit care these costs were €11.80, €53.10, and €97.40, respectively, which represents 10.6% of overall per diem intensive care unit costs. Therefore, these costs are negligible for cost analysis.

A cost-effectiveness analysis from the viewpoint of the hospital provider using only costs and not charges was performed. Costs instead of charges were used because charges may vary considerably between different countries and may also be a major subject of change by time, while costs will experience less variability. Costs of lost labor were excluded because of the chosen perspective of a hospital provider. The main outcome measure was the rate of anastomotic leakage, while associated mortality was too low to serve as an outcome measure. Quality of life was not considered in the present study because quality-adjusted data do not alter overall results, especially when stomas are created for a limited period.[7]

Discounting was unnecessary because costs and effectiveness were recorded during the 1-year period. The price year for the present study was 2000. To deal with uncertainty a 1-way sensitivity analysis was performed varying key input factors. The range of changes was based on confidence intervals for these data and logic.

For statistical analysis, the χ^2 test was used for qualitative variables, while for continuous risk factors, the Mann-Whitney and *t* tests were applied when appropriate. For the comparison of the 3 groups of patients, the Kruskal-Wallis test and 1-way analysis of variance were applied. Differences were considered statistically significant at $P < .05$. Data are given as mean (SEM).

RESULTS

Nineteen (27%) of 70 patients with rectal cancer received defunctioning stomas after undergoing LARs. In these patients the duration of the operation was considerably longer (208 [16.1] vs 180.4 [9.7] minutes; $P = .13$). However, there was no major difference between patients who had defunctioning stomas and patients who had no colostomy in terms of comorbidity (Table 1). Patients who experienced anastomotic leakages after undergoing LARs without stomas needed a significantly longer duration of hospital care ($P = .01$) and intensive care unit care ($P < .001$), whereas these patients did not have a tumor closer to the anal verge (**Table 3**).

Additional costs for patients with stomas were derived from further hospitalizations that were necessary for the closure of these stomas, and there was likewise an indispensable additional stay for patients after anastomotic dehiscence. Stoma-related complications did not contribute to the major additional costs.

Overall, there was a major difference in mean costs of treatment between an LAR carried out with or without a defunctioning stoma (€13 985 vs €10 391; $P < .001$). However, mean costs of treatment were 5-fold higher in patients who developed an anastomotic leakage after undergoing an LAR (€42 250) when compared with patients who underwent an LAR without a stoma and without dehiscence (€8400; $P < .001$).

Therefore, important cost drivers after undergoing an LAR and most important factors for cost minimization were (1) anastomotic leakage and (2) a defunctioning stoma. An anastomotic leakage rate of 16.5% in patients without stomas would be necessary to balance mean treatment costs of LARs with defunctioning stomas (ie, for the group without stoma but a leakage rate of 16.5%, the cost is €13 985.60 vs €13 984.50 for the group where a stoma was created for every patient and there was no leakage; costs being nearly identical). A scenario analysis shows that a worst-case scenario would be associated with 2.5-fold higher overall costs of an LAR compared with a best-case scenario, while an incremental cost-effectiveness ratio would be highly negative in these patients, which means an additional saving of costs for every stoma created (**Table 4**). Reducing the anastomotic leakage rate below 3% (best-case scenario) would lead to an unacceptably high incremental cost-effectiveness ratio of €158 705 per leakage avoided through the creation of a defunctioning stoma.

One-way sensitivity analysis demonstrates robustness of the study overall by changing various key input factors along a plausible range of data (**Table 5**). Duration and costs of intensive care unit care were the only factors that may considerably alter a proportion of overall costs between the groups of patients.

CONCLUSIONS

Better surgical techniques made preservation of continence possible in a higher proportion of patients with rec-

Table 4. Cost Analysis for 3 Scenarios From Published Studies and Incremental Cost-effectiveness Ratio for Various Leakage Rates and Associated Scenarios*

Scenario	Stoma Rate, %	Overall Leakage Rate, %	Mean Overall Costs, €
Best-case scenario[16]	9.0	2.6	9.787
Best guess[6]*	26.7	4.3	11.367
Worst-case scenario[5]	50.0	32.0	21.578

Strategy (n = 100)	Costs, €	Anastomotic Leakage Rate, %	Leakage Avoided, %	Additional Costs, €	Incremental Cost-effectiveness Ratio, €
No stoma					
Best guess†	1 039 160	5.9	0	NA	NA
Best-case scenario	938 205	2.9	0	NA	NA
Equal overall costs	1 398 560	16.5	0	NA	NA
Worst-case scenario	2 464 840	48.0	0	NA	NA
Stoma					
Best guess†	1 398 450	0	5.9	359 400	60 915
Best-case scenario	1 398 450	0	2.9	460 245	158 705
Equal overall costs	1 398 450	0	16.5	−110	−7
Worse-case scenario	1 398 450	0	48.0	−1 066 390	−22 217

Abbreviation: NA, not applicable.
*Leakage rates in the scenario analysis refer to the whole study population, while for incremental cost-effectiveness ratios leakage rates refer to patients without a stoma.
†This value is based on our treatment results of rectal cancer.

Table 5. One-way Sensitivity Analysis to Demonstrate the Change in Overall Costs Due to Changes of Various Input Parameters*

Input Parameters	Change of Input Parameters	Change in LAR Without Stoma	Change in LAR With Leakage	Change in LAR With Stoma
Duration of hospital care	10%	402	1343	669
Duration of ICU care	10%	46	2548	168
Operating time	10%	398	723	592
Costs of hospital care	20	345	833	561
Costs of ICU care	150	44	2500	158
Costs of OP, min	3	541	980	804

Abbreviations: ICU, intensive care unit; LAR, lower anterior resection; OP, operation.
*Data are given in Eurodollars unless otherwise indicated.

tal cancer. Nevertheless, there is no common agreement about clear criteria for defunctioning stomas. Defunctioning stomas are created in up to 73% of the patients treated to avoid complications due to anastomotic dehiscence. Nevertheless, clinical anastomotic leakage may occur in up to 32% of these patients.[5] Anastomotic leakage may also occur in patients with defunctioning stomas and may be explained by incomplete fecal diversion, but reoperations are necessary in a lower proportion of these patients.[5,8-14] Comparing data in the literature, there is no direct correlation between the rate of stomas and the rate of anastomotic dehiscence.[2-6,8-21] A rate of defunctioning stomas from 0% to 9% can also achieve a low rate of anastomotic leakage as low as 3% to 7.6%,[16-18,20] which reflects that surgical results of an LAR depend more on the skill of the surgeon rather than on the characteristics of the patient. Others, who experienced a leakage rate of 16% to 32% despite of a rather high rate of stomas (28% to 55%) should reflect on their surgical technique.[5,8,9,11]

A high risk for anastomotic complications could be identified in obese male patients with very low anastomoses up to 6 cm from the anal verge.[4,12,13,17] Other criteria may be difficult dissection, incomplete doughnuts, and tension on the anastomosis.[16] Age may also correlate with anastomotic leakage[18] that as a trend could also be observed in our patients.

In patients who underwent an LAR for rectal cancer, fecal diversion conferred a significant survival disadvantage at 5 years after surgery that could be prevented by delayed closure of the stoma.[22] In our patients a tumor in the distal third of the rectum led significantly more often to a defunctioning stoma, but other known risk factors were not significantly different between the groups (Table 1 and Table 2). Anastomotic leakage never occurred in these high-risk patients but only in patients with more proximal tumors, those who did not receive preoperative radiotherapy, and those who had a body mass index of less than 35.

I am only aware of 1 study with regard to cost-effectiveness of defunctioning stomas in LAR[1] that found that diverting stomas may double the costs of an LAR. This higher difference can be explained by a longer initial hospital stay in patients with a stoma and by a very low rate of anastomotic leakage.

Our data suggest that low anastomotic leakage rates should also lead to a lower rate of diverting stomas because overall costs are significantly higher in LARs with a stoma and an incremental cost-effectiveness ratio of more than €60 000 is too high to justify uncritical use of stomas. In institutions with anastomotic leakage rates of 16.5% or higher, the incremental cost-effectiveness ratio would be 0 or even a negative sum. But overall costs would be unacceptably high; performing diverting stomas in every patient would be the only way to reduce these high costs.

Applying known criteria for a higher risk of anastomotic leakage, a rate of defunctioning stomas would be 10% or less. An associated anastomotic leakage rate lower than 10% should be a benchmark for an LAR in terms of cost-effectiveness and quality control. Applying this benchmark would limit overall costs to €12 000 per patient treated.

In reviewing the literature a much higher stoma rate of 50% or more has had no additional effect on reducing anastomotic leakage.[3-5,9,11] It is questionable if LARs should be carried out in institutions where anastomotic leakage rates of 15% or more are associated with a rate of defunctioning stomas of 30% or more. Nevertheless, a higher rate of defunctioning stomas can be accepted if it proves to lower the rate of anastomotic leakage because the most important cost driver is anastomotic leakage. Besides obesity, male sex, and a low rectal tumor, there are other less clearly defined criteria such as technical difficulties and surgical experience that may contribute to local complications of LAR. Therefore, patients prone to anastomotic dehiscence are difficult to define. Instead of this, every surgical institution should apply benchmarks for quality control and cost-effectiveness.

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