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ORIGINAL ARTICLE

# Validation of a score for the early diagnosis of anastomotic leakage following elective colorectal surgery



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## KEYWORDS

Anastomotic leakage;  
Colorectal surgery;  
Score;  
Post-operative complication;  
Failure to rescue

## Summary

**Introduction-Aim:** Anastomotic leakage (AL) is the most feared complication after colorectal surgery. Its prognosis is related to early recognition and post-operative management and should be based on the concept of "failure to rescue". The aim of the present study was to validate the "DULK" diagnostic score for AL, developed in The Netherlands.

**Material and method:** From June 2012 to June 2013, 100 consecutive patients were included in a prospective study according to the post-operative care protocol developed by den Dulk et al. The score is based on several laboratory and clinical items recorded daily.

**Results:** Among the 100 patients, 12 developed a post-operative AL (12%) with a specific mortality rate of 16.6% (2 patients). A DULK-score > 3 was good criteria for early diagnosis of AL with a sensitivity of 91.7%, a specificity of 55.7%, a positive predictive value of 22%, a negative predictive value of 98%, and an area under the ROC curve of 0.83. If used routinely, the DULK-score would allow diagnosis of AL 3.5 days earlier than clinical judgment alone. The DULK-score was superior to common diagnostic criteria described in the literature such as the C-reactive protein or procalcitonin, in terms of both sensitivity and specificity.

**Conclusion:** The DULK-score is, at present, the most reliable instrument for early diagnosis of AL after colorectal surgery and should be integrated into risk management health policies aiming to improve the quality of care according to the "failure to rescue" concept.

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## Introduction

Anastomotic leakage (AL) is the most dreaded complication after colorectal surgery because it increases surgical mortality, lengthens hospital stay [1,2], alters functional outcome and is a factor of local recurrence after carcinologic treatment of colorectal tumors [3–5]. While prevention remains the best approach, rapid

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management (early diagnosis and adapted treatment) is emerging as the best way to reduce severity [6] according to the “failure to rescue” concept [7,8].

Several clinical, or laboratory parameters (C-reactive protein, [9–11], procalcitonin [11,12]) criteria or scores have been published. Among the latter, the “Dutch leakage-score” or “DULK-score”, published by den Dulk et al., was validated prospectively for colorectal surgery and was found to lead to reduced mortality and early diagnosis of AL, compared to a historical series [13].

The goals of this study were to analyze the external validity of this score outside of the Netherlands (where the score was devised) in order to improve risk management in elective colorectal surgery, and try to reduce mortality, according to the “failure to rescue” concept.

## Material and method

### Study population

This was a prospective monocenter clinical study that addressed patients undergoing elective colorectal surgery. Procedures involved benign (resection of colorectal polyps, extended ischemic or infectious colitis, diverticular disease, Crohn’s or ulcerative colitis) as well as malignant disease (colonic or rectal cancer), with intra-peritoneal or infra-peritoneal anastomosis protected or not by a stoma.

Inclusion criteria were patients  $\geq 18$  years old, undergoing elective colorectal surgery with anastomosis. Non-inclusion criteria were emergency operations and elective stoma reversals.

### Post-operative protocol

Post-operative surveillance was standardized: inclusion was on the day of operation (D0) and the day after operation (D1) was the initial date for the measured parameters. Each clinical and laboratory parameter, easily culled at bedside, was recorded day-by-day. These items were summed and weighted to determine the probability of AL, or the “Dulk-score” (Table 1). This score was calculated every day.

If the score was calculated more than one time for 24 h, only the highest score was used, i.e. the score most likely associated with colorectal AL. The higher the score, the more likely AL would occur. However, as the “DULK-score” had not been previously validated in our unit or by any other teams in France, we decided to leave decisions regarding management of each patient up to the individual attending surgeon.

Patients with clinically proven AL (fecal discharge via the drainage or the wound) were not integrated into the decision tree (Table 2), as management was necessary in any case.

Two intervals were measured:

- the interval between D0 and the first day of symptomatic AL (defined as the day when the DULK-score was  $> 3$ );
- the interval between the 1st day of symptoms of AL and the day of confirmation of AL by imaging or when reoperation was performed (considered as the interval until the diagnosis was made).

All patients had a routine visit four weeks after surgery, and were followed for three months or longer, either by outpatient visits or by telephone.

**Table 1** Calculation of the DULK-score every 24 h.

Temperature $> 38^{\circ}\text{C}$	1 point
Pulse rate $> 100$	1 point
Respiratory rate $> 30/\text{min}$	1 point
Oliguria (diuresis $< 700\text{ mL/d}$ )	1 point
Agitation or lethargy	2 points
Clinical deterioration	2 points
Ileus	2 points
Gastroparesia	2 points
Evisceration	2 points
Abdominal or parietal pain	2 points
Elevated WBC count ( $10^3/\text{mL}$ ) or CRP ( $\text{mg/L}$ ) $> 5\%$	1 point
Elevation blood creatinine or urea $> 5\%$	1 point
Enteral nutrition tube OR Parenteral nutrition	1 point 2 points

WBC: white blood cell; CRP: C-reactive protein.

If the patient requires enteral alimentation in addition to parenteral alimentation, only enteral alimentation is counted, i.e. one point.

### Outcome criteria

The main endpoint of this study was the efficacy of the score for early detection of AL in patients who had undergone elective colorectal resection. The efficacy was evaluated by its sensitivity, specificity, positive and negative predictive values and the area under the ROC curve (AUC).

Secondary outcome measures included:

- immediate (during the operation), early (during post-operative hospital stay) and late (up until three months post-operative) complications;
- the duration of hospital stay after operation;
- need for care, re-hospitalization, planned or not, during the 90 days after operation;
- comparison of the DULK-score to other evaluation criteria in the literature, such as C-reactive protein (CRP) or other clinic-biological criteria.

### Statistical analysis

Statistical analysis was performed with STATA v12 (Stata-Corp, College Station, Texas) including:

- descriptive statistics such as mean and standard deviation, median and range for quantitative variables, prevalence and percentages for qualitative variables;
- univariate analysis to determine the predictive factors of AL after elective colorectal surgery included the Student or Kruskal-Wallis test, the  $\text{Chi}^2$  or Fisher exact test to compare qualitative parameters between patients with or without AL, as appropriate. All factors with  $P < 0.10$  were included in multivariable analysis;
- step-by-step logistic regression multivariable analysis.

After multivariable analysis, ROC curves were established and the AUC were compared. Lastly, a predictive threshold for AL was determined according to the ROC curve (highlighting a strong sensitivity). The cut-off point and the

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