REGION KRONOBERG

Local validation of an anastomosis leakage score

Niklas Holmlöv, ST-läkare, Kirurgi, Ljungby lasarett,
niklas.holmlov@kronoberg.se

Handledare: Andreas Martinsson, läkare, med.dr,
Kardiologi, Sahlgrenska universitetssjukhuset

Innehåll

Introduction

Bowel resection is a common procedure with in general surgery. It is performed as treatment for malignant disease, inflammatory bowel disease or part of emergency surgery for bowel obstruction or trauma. During 2019 gastrointestinal (GI) surgery accounted for 24,601 individual operations in teenage or adult patients in Sweden.[1] A bowel anastomosis is a common end result after such surgery, One of the most feared complications in general surgery is anastomotic leakage (AL) or rupture which leads to deterioration of the patients' clinical condition and worsens outcomes.[2] The symptoms of AL can often be vague and nonspecific, making early diagnosis challenging, however, timely diagnosis of AL is important to reduce mortality since untreated AL can lead to sepsis and death.[3-4]

In modern studies the incidence of colonic AL varies between 2,4-28% depending on patient selection.[5] Rectal surgery has a slightly higher incidence of AL and enteroenteric anastomoses have a lower risk of leakage.[5] AL has been reported to be cause up to one third of postoperative mortality following bowel surgery.[2]

The severity of AL can be graded according to the definition proposed by Rabhari et al, originally constructed for anterior resection of the rectum.[6] This system grades the leakage from A to C where A requires no specific treatment and C requires re-laparotomy. The treatment of AL varies between re-operation with resection and renewed anastomosis, sometimes with fecal diversion through a protective stoma and more conservative treatment with drainage, antibiotics and/or permission of fistula formation.[4,6,7] Time until diagnosis of AL can often determine the treatment options available since untreated AL increases the difficulty and risk of a re-operation.[8]

Dulk et al. have designed a postoperative scoring system for early detection of AL and proved its usefulness for early diagnosis of AL in colorectal surgery, including ileocolic, ileorectal and colocolic anastomosis. It was shown both to reduce the time to diagnosis from 4 to 1.5 days and to reduce the post-operative mortality following bowel surgery.[9,10] The DULK score is based on clinical parameters and laboratory results assessed on a daily basis. A high score signals the need for further evaluation or treatment, such as radiologic imaging or surgical intervention (Table 2). A low score has a high negative predictive value for AL.[10] The DULK score has since its publication been validated by the original Dutch authors as well as in a French single center study who reported an optimal cut-off value of >3 points for suspected AL.[11] It has not previously been validated in a Swedish, rural, setting.

Aim of this study

To validate the DULK score as a tool to identify anastomotic leakage in post-operative patients after bowel surgery locally at Ljungby Lasarett.

To evaluate whether using the DULK score improves patient outcomes after bowel surgery at Ljungby lasarett.

Methods

The study was performed at Ljungby Lasarett, a Swedish rural hospital with a catchment area of 55.000 persons. All active surgeons and surgical residents are general surgeons, no certified colorectal surgeons are employed. Emergent and elective surgery, including both benign and malignant bowel disease (excluding rectal cancer) is performed at the center. During the time of the study, there were six attending general surgeons and 4 surgical residents employed at the hospital.

Study population

All patients undergoing surgery with bowel anastomosis at Ljungby Lasarett from April 2017 until March 2019 was evaluated with the DULK score (Table 1) postoperatively. Small bowel resections and anastomosis due to reasons such as malignancy or ischemia was included in the study. Patients who underwent laparoscopic gastric bypass surgery or simple reduction of a loopileostoma was excluded due to the fact that these interventions have a very low frequency of acute complications and a short post-operative length of care. A total of 75 patients where included prospectively. 50 consecutive patients undergoing the same procedures in the same hospital from March 2015 until March 2017 was used as controls. The study cohort was followed with the score for at least 3 days postoperatively. Patients who weren't followed with the DULK-score for at least 3 days were excluded (N=8). The study is a part of an ethically approved clinical quality of care control program (Reference number – 19RGK385) at Ljungby Lasarett.

Data relevant for risk calculations of post-operative complications were collected from the patient records, including parameters from the DULK score in the study group whereas only descriptive characteristics could be collected in the control group. The collected characteristics consisted of age, sex, ASA score, type of anastomosis, elective or emergency surgery and if the patient was an active smoker. The patients in the study group was included prospectively on the day of their surgery, the score was calculated starting the first postoperative day and was thereafter routinely calculated at rounds every 24h. The DULK score threshold to raise suspicion of AL had a cut off of 4p as recommended in the original study, the individual parameters used in the DULK score

can be found in Table 1. American Society of Anesthesiologists (ASA) score was used to evaluate preoperative morbidity.[12]

Statistical analyses

Differences in the clinical characteristics between groups were tested with Student's t-test. Pearson correlation was used to test individual characteristics and their correlation with length of stay and anastomotic leakage.

Categorical variables are presented as frequencies and percentages. Continuous variables are presented as means with standard deviation or medians with interquartile range, as appropriate. Normal distribution was visually evaluated using histograms. ROC-curves where constructed and the area under the curve (AUC) examined when evaluating the optimal threshold for the score. Sensitivity was prioritized above specificity. Negative and positive predictive values was recorded. A p-value of <0.05 was considered statistically significant. Statistical analysis was performed using PSPP version 42.2.3.

Outcomes

Outcomes considered were immediate and early complications (mortality and re-operation) after bowel surgery with anastomosis and length of post-operative in-hospital stay before and after introduction of the DULK score.

Results

There were no statistically significant differences between the study cohort and control group (Table 3). 21.3% and 22% of the study cohort and controls respectively, had an ASA-score of ≥3 indicating severe systemic disease. Out of the 75 included patients in the study group and the 50 patients in the control group, 8 (10.6%) and 4 (8.0%) had anastomotic leakage.

A higher ASA-score was more common in patients with AL where 37.5% had an ASA-score ≥3. Patients with AL more commonly were male and smokers. On average they had a DULK score of 5.0 (±3.16) compared to 1.9 (± 1.80), Table 3. The type of anastomosis had no significant correlation to the risk for AL but the highest incidence of leakage was seen in the colon anastomosis group with 4 (23.5%) and 2 (13.3%) for the study cohort and controls respectively. The mortality in the groups with AL where 12.5% in the study group and 50% in the control group. All AL but one led to re-operation.

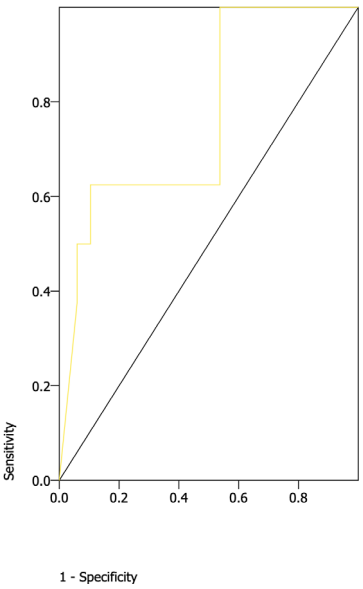
Length of stay

The length of stay (LOS) increased with AL (p=.003 CI 95% 4.81-59.73). The median LOS was 7 days (range 2-21) for patients without leakage and 37.5 days (range 7-113) for patients with leakage in the study group. In the control group the median LOS was 5 (3-45) and 20 (14-28) respectively. Mean LOS increased with age (Pearson's .24 p=.047) in the non-AL study group but not in the control group. LOS was not related to age in patients with AL. ASA was an independent predictor of LOS both in the study group (Pearson's .32 p=0.009) and the control group (Pearson's .45 p=0.002). A higher DULK score was predictive of LOS in the no-AL group (Pearson's .51 p<0.001).

Performance of the DULK score

The highest recorded DULK score per patient had a significant relation to AL (p=.019). Using the highest recorded DULK score the days before diagnosis of AL or discharge without AL a ROC curve was constructed for the correlation of the presence of AL. The AUC for the DULK score was .83 (95% CI .71-.95). A threshold of 2 points had a sensitivity and specificity of 100% and 46% respectively resulting in a positive predictive value of 18% and a negative predictive value of 100%. Using a 3 point threshold resulted in a sensitivity of 63% and a specificity of 76%. Using a threshold of 4 points resulted in a sensitivity of 50% and a specificity of 84% respectively.

ROC DULK score vs AL



Area under curve 0.83

The median time to diagnose AL using the score as suggested in the original trial was 3.5 days (IQR 2.0). In the control group, the median time to diagnosis was 3 days (IQR 1.5). Mortality was lower in the study group than the control group as reported above.

Discussion

In their original study[9], Dulk et al. showed that the DULK score was useful for identifying an anastomotic leakage early and thereby improving patient outcomes. The authors proposed a cut off-value of four points for the score to be considered positive. In this study we found that a score of four points only had a sensitivity of 63% and the score did not produce significant positive results with regards to timely discovery of AL. While a negative ROC predictive value of 100% is good, the usefulness of the score lies in a high sensitivity and a good positive predictive value. Even though the average DULK score was higher in patients with AL as shown in Table 3 ($p=0.028$), the threshold had to be lowered to two points in order to achieve an adequate sensitivity. This made the score non-specific in our setting. The positive predictive value of 18% for a two point threshold was low. However, other conditions including infections or abscesses where present in the majority with high scores, and a high score was indicative of a longer hospital stay even in absence of anastomotic leakage making it useful for identifying high-risk individuals after bowel surgery.

The leakage rates in our study are on par with rates reported in other studies, the mortality was lower than ordinary in the study group but higher in the control group. 10,11 The score failed to find AL earlier, in fact AL was found on average 12h later compared to the control group. LOS was found to be on average one month longer with AL in the study group. In the control group the LOS with AL was shorter, this however is skewed by the higher mortality in the control group and no conclusion can be drawn from this considering the small number of cases. The single patient that died in the study group did have an above threshold score, but there was no significant correlation between high DULK scores and mortality.

The risk of anastomotic leakage was highest with a colonic anastomosis in this study. Due to the small sample size significance could not be achieved and hence this endpoint could not be reliably answered and other factors could be as important. Advanced age and a high ASA score was indicative of a longer post-operative hospital stay, but surprisingly had no significant impact on the risk of AL. Smoking was more common in the group with AL, but did not give rise to a significantly higher risk in itself.

Limitations

This was a small single center study performed in a rural centre leading to exclusion of certain patient cohorts. Some anthropometric parameters where missing. The small study population renders type 1 errors possible, thereby limiting the power of the study.

Conclusion

In the current study, the DULK score as used in previous trials could not be used in the early detection of AL. After the introduction of the DULK score patient outcomes have improved, but no clear association between the introduction of the DULK score and improved outcomes could be established in the study.

Table 1. DULK parameters and points given

Item	DULK score threshold	Points
Fever	>38°C	1
Heart rate	>100/min	1
Respiratory rate	>30/min	1
Urinary production	<30ml/h or 700ml/d	1
Mental status	Agitation or lethargic	2
Clinical condition	Deterioration	2
Bowel obstruction	Present	2
Gastric retention	Present	2
Fascial dehiscence	Present	2
Abdominal pain other than wound pain	Present	2
Signs of infection	CRP >200	1
Kidney function	increase of >5% in creatinine	1
Nutrition	Total parenteral nutrition	2

Table 2. DULK surveillance protocol

<3 points	**no action**		
4-7 points	Renewed exam	Labs +/- cultures	Computed tomography within 12h
>8 points	CT-scan	Surgical exploration	

Table 3. Patient descriptive characteristics

Parameter	Study	Control
Gender (%) -Male -Female ÷	 35 (46.7) 40 (53.3)	 24 (48) 26 (52)
Age mean	66.9	67.8
Smoking %	16	14
ASA mean ± SD	2.03 ± 0.7	1.97 ± 0.7

Table 4. AL characteristics compared in the study group

Parameter	AL	non-**AL**
Gender (%) -Male -Female	 5 (62.5) 3 (37.5)	 30 (44.8) 37 (55.2)
Age mean	66	67
Smoker %	37.5%	13.5%
ASA mean ± SD	2.25 ± 1.04	2 ± 0.65
Mean DULK **score**	5 ± 3.16	1.9 ± 1.80

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