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ORIGINAL SCIENTIFIC REPORT

Quality Improvement of Damage Control Laparotomy: Impact of the Establishment of a Single Korean Regional Trauma Center

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Abstract

Background Damage control laparotomy (DCL) is a lifesaving technique to minimize the lethal triad of coagulopathy, hypothermia, and acidosis. The government has nominated and supported our center as one of the regional trauma centers of South Korea since 2014. This study aimed to investigate the improving outcomes of patients undergoing DCL before and after the establishment of the trauma center.

Method The period from January 2011 to December 2017 was divided into pre-trauma center (pre-TC) (2011–2013) and trauma center (TC) (2014–2017) periods. Multivariable logistic regression was performed to identify the risk factors and risk-adjusted cumulative sum (RA-CUSUM), and graphs were used to monitor the change in mortality.

Result Of the 485 patients who underwent trauma laparotomy, DCL was performed for 119 patients (24.5%). The operation time (99 vs. 80 min, $p = 0.022$), time from admission to operation (125 vs. 112 min, $p = 0.010$), time from admission to first treatment (119 vs. 99 min, $p = 0.004$), and time from admission to first transfusion (70 vs. 52 min, $p = 0.009$) were significantly shortened in the TC period. The ratio of plasma to packed red blood cells in massive transfusions (≥PRBCs 10 units within the first 24 h) was significantly increased in the TC period (0.56 vs. 0.72, $p = 0.004$). RA-CUSUM curves revealed that the risk-adjusted 30-day mortality improved and then plateaued in the TC period.

Conclusion After the implementation of a trauma center, more prompt intervention and damage control resuscitation could be achieved. Moreover, risk-adjusted mortality of DCL was improved.

Introduction

Damage control laparotomy (DCL) has been a useful tool for the care of severely injured patients, and it has been adopted widely [1]. The concept of "damage control" has contributed to improved mortality rates in trauma laparotomy [1–4]. Although the efficacy of DCL with major abdominal trauma remains unclear because of a lack of prospective data [5, 6], DCL and damage control resuscitation (DCR) are regarded as essential treatments for severe trauma patients [1, 7]. In South Korea, the government-led implementation of trauma centers has started, and many surgeons have started to work in the trauma field since 2012 [8]. This could be a breakthrough in the overall trauma system in South Korea. Furthermore, Korean trauma surgeons were the first to take a major initiative to treat severe trauma by introducing the concept of damage control. Here, we investigated the improvement of damage control and mortality using risk-adjusted cumulative sum

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analysis (RA-CUSUM). Through this study, we aimed to assess the impact of trauma center implementation.

Materials and methods

The present study was approved by the institutional review board of our institution. We reviewed a prospectively collected trauma database between January 2011 and December 2017 at our trauma center. We searched for trauma patients who underwent DCL. Patients who died before or during the first surgery, those who did not undergo laparotomy with an open abdomen, those who underwent only pre-peritoneal pelvic packing without laparotomy, and those who transferred to another hospital were excluded from the study.

Patients' demographic and clinical data including injury mechanism, age, sex, laboratory findings, vital signs, Glasgow Coma Scale (GCS), Injury Severity Score (ISS), Abbreviated Injury Scale (AIS) score, transfused blood components, postoperative outcomes, and time parameters related to surgery, angiography, and transfusion were collected and analyzed. Because some patients were intubated before admission, we used the best motor score for scoring of mental status instead of full GCS [9].

Our center was nominated as one of the Regional Trauma Centers of South Korea in 2013. From January 2014, we have received financial support from the government for manpower, equipment, and facilities. Two dedicated trauma bays and two operating rooms that were close to the trauma bay were equipped for work by dedicated trauma staff. The massive transfusion protocol was newly adopted by the trauma staff. As of January 2014, we divided our study into two periods: pre-trauma center (pre-TC) (2011–2013) and trauma center (TC) (2014–2017) periods. Until December 2013 (pre-TC period), trauma surgeries were performed by various general surgeons who specialized in gastrointestinal, hepatobiliary, endocrine, pediatric, and vascular surgery. Moreover, the operator of trauma surgery had been decided not by the surgeon's specialty but by a surgeon's duty. From January 2014 until now (TC period), all trauma surgeries and all trauma patients have been managed by attending trauma surgeons in our center.

During the TC period, the concept of DCR was first adopted by trauma surgeons. The accepted principles of DCR were as follows: (1) avoid or reverse hypothermia, (2) avoid delays in surgical or angioembolization, (3) transfuse blood components to secure a 1:1 ratio of plasma, (4) minimize crystalloid administration, and (5) target low–normal blood pressure before definitive hemostasis [7].

DCL was performed for patients with unstable vitality, uncontrolled bleeding, coagulopathy, acidosis, excessive bowel edema, and hypothermia. DCL first involved the abbreviated laparotomy followed by resuscitation in the intensive care unit and definite reoperation with abdominal closure. [1].

Statistical analysis

Continuous data are presented as median with 25th and 75th interquartile range; data were analyzed using Mann–Whitney *U* test. Categorical data are presented as proportions. Proportions were compared using the Chi-squared test or Fisher's exact test as appropriate. Univariate and backward stepwise multivariable logistic regression was used to identify significant preoperative risk factors associated with postoperative mortality. To adjust for confounding factors, variables with a univariate p value < 0.20 were included in the multivariable analysis. A p value < 0.05 was considered statistically significant. All statistical analyses were performed using Microsoft Excel (Microsoft Corporation, Seattle, WA, USA) and IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA).

RA-CUSUM

To evaluate the improvement of surgical performance and adjust the individual preoperative risk of mortality, which varies significantly among patients, the RA-CUSUM analysis was performed on the basis of the logistic regression model [10, 11]. CUSUM was calculated as follows: $Sn = (Xi - p0_i)$, where $Xi = 0$ for success (patient who survived) and 1 for failure (patient who died), and $p0_i$ denotes the predicted probability of failure for operation, calculated from a multivariable logistic regression model. A receiver operating characteristic (ROC) curve analysis was performed for the predictive performance of logistic regression model. The graph starts at zero and is plotted from left to right on the horizontal axis. The curve moves up by $1 - p0_i$ for every case with mortality (penalty) and down by $p0_i$ for every survived case (reward). By this curve, improvement or deterioration of surgical outcome would be identified intuitively with correction of selection bias. The cumulative sum (CUSUM) procedure is a graphical method that is widely used for quality monitoring [10]. Because the standard CUSUM procedure is simply based on the observed surgical outcome, we therefore conducted the RA-CUSUM procedure for risk adjustment.

Results

From January 2011 to December 2017, 16,737 trauma patients were admitted to the emergency room of our hospital. Of these, 485 patients underwent laparotomy by general surgeons or trauma surgeons. DCL was performed in 119 patients (24.5%, 119/485). The 30-day mortality of DCLs was 42.0% (50/119), while that of all laparotomies was 14.4% (70/485). The change in the 30-day mortality rate of all laparotomies and DCLs is shown in Fig. 1. The 30-day mortality of DCL decreased per year, but has increased since 2015. The ratios of DCL to all laparotomies were oscillating. However, the 30-day mortality of all laparotomies including DCLs decreased significantly per year (p for trend = 0.03).

The patients' clinical characteristics between pre-TC and TC periods are shown in Table 1. And the process (time values) and transfusion requirements are shown in Table 2. The transfusion of packed red blood cells (PRBCs) was significantly reduced in TC period. Moreover, the ratio of fresh frozen plasma (FFP) to PRBC in the first 24 h was significantly increased in the TC period (Table 2). In patients with massive transfusions ($\geq$PRBC 10 units within the first 24 h), the FFP/PRBC ratio was also significantly increased in the TC period (Table 3). Furthermore, the time from admission to the first transfusion was significantly shortened.

The intraoperative crystalloid fluid infusion was not significantly different in the pre-TC and TC periods [5000 mL (IQR, 2600–9000 mL) vs. 4900 mL (IQR, 3500–6700 mL), $p = 0.619$]. However, the intraoperative colloid fluid infusion was significantly reduced in the TC period [1000 mL (IQR, 500–1750 mL) vs. 275 mL (IQR, 0–500 mL), $p < 0.001$]. Similarly, the postoperative crystalloid fluid infusion ($\leq$24 h postoperatively) was also not significantly different in both groups [4892.5 mL (IQR, 3232–6093 mL) vs. 4619.5 mL (IQR, 3678.5–5515.5 mL), $p = 0.502$], and the postoperative colloid infusion ($\leq$24 h postoperatively) was significantly reduced in the TC period [900 mL (IQR, 500–1600 mL) vs. 250 mL (IQR, 50–260 mL), $p < 0.001$].

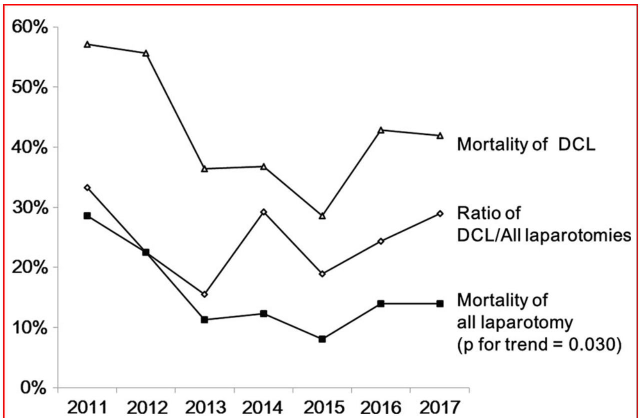

Fig. 1 30-Day mortality of damage control laparotomy (DCL) and all trauma laparotomies including non-DCL

After adjusting the preoperative risk of mortality, the individual probability of mortality was calculated by multivariable analysis (Table 4). Based on this probability, the CUSUM graph is presented in Fig. 2. Both unadjusted CUSUM (using single probability which is 42.0% of 30-day mortality for all DCL cases) and RA-CUSUM (using individual probability) were presented. The CUSUM graph showed an upward slope in the pre-TC period. At the 39th patient (arrows) in the TC period, a downward inflection was observed. In the TC period, compared with the unadjusted CUSUM chart, the RA-CUSUM graph showed a downward fall reaching the negative score earlier and later reached a plateau. The ROC curve analysis for predictive performance is illustrated in Fig. 3.

Discussion

DCL has been widely performed in the field of trauma surgery [1] since the term "damage control" was first introduced in 1993 [12]. Although DCL is a very useful concept for exsanguinated patients, some investigators disputed its possibility of overuse and latent harmful effect [6, 13]. However, DCL is a widely accepted procedure and has become one of the most crucial concepts for either trauma or non-trauma surgeons [14]. In contrast to the enthusiasm for the DCL, high-level evidence for this procedure has been very limited. A recent systematic review by Cochrane collaboration reported that there have been no prospective studies that addressed damage control surgery for trauma patients [5]. Because of the emergent situation and ethical issues, it is difficult to perform a randomized control trial of damage control surgery. Nevertheless, even with the limited high-level evidence, DCL seems to be essential in preventing the deaths of major trauma patients. However, the improvement in the performance of DCL (in other words, the "learning curve") has not been estimated in previous studies. In general, the portion of DCL in trauma laparotomy is relatively low (up to 30%, 24.5% in the present study) [4, 6, 14]. Consequently, this small sample size is insufficient for estimating the learning curve of a single surgeon. Therefore, we tried to estimate the performance of DCL at the hospital level in the present study. Because the surgical outcome is not affected by only a single surgeon's skill but also the entire systemic quality of the hospital and regional society, it should be ideally

Table 1 Comparison of patient demographics and preoperative values between pre-trauma center (pre-TC) and trauma center (TC) periods

	Pre-TC (N = 34)	TC (N = 85)	p
Injury mechanism			0.535
Blunt	31 (91.2)	76 (89.4)	
Penetrating	3 (8.8)	9 (10.6)	
Age, years	50 (42–61)	54 (38–67)	0.294
Sex, male	27 (79.4)	61 (71.8)	0.491
First laboratory findings on admission			
Base excess (-)	10.9 (5.7–16.4)	10.1 (5.9–15.3)	0.628
pH of ABGA	7.23 (7.16–7.38)	7.28 (7.17–7.35)	0.764
Hematocrit	28.9 (24.7–34.8)	28.7 (23.8–33.9)	0.709
Preoperative cardiopulmonary resuscitation	6 (17.6)	10 (11.8)	0.388
Initial vital signs on admission			
Systolic blood pressure	70 (50–90)	70 (0–80)	0.717
Pulse rate			0.596
61–120 beat/min	25 (73.5)	56 (65.9)	
>120 beat/min	4 (11.8)	13 (15.3)	
31–60 beat/min	0 (0)	5 (5.9)	
0–30 beat/min	5 (14.7)	11 (12.9)	
Body temperature °C	36.0 (36.0–36.2)	36.0 (36.0–36.2)	0.367
Best motor score of GCS	6 (1–6)	6 (4–6)	0.331
Intubated before admission	7 (20.6)	8 (9.4)	0.126
Injury scale			
Injury severity score	25 (16–29)	25 (17–34)	0.634
Abdomen AIS	4 (4–4)	4 (4–4)	0.074
Head AIS	0 (0–0)	0 (0–0)	0.855
Chest AIS	1 (0–3)	2 (0–3)	0.619

Values are presented as n (%) or median (25th interquartile range to 75th interquartile range)

ABGA arterial blood gas analysis, *GCS* Glasgow Coma Scale, *AIS* abbreviated injury scale

evaluated by a multilevel analysis, and a multicenter prospective study should be needed.

In the present study, to minimize the selection bias, the preoperative risk that affects mortality should have been adjusted. The RA-CUSUM chart is designed to detect the risk-adjusted mortality after DCL. As shown in previous studies [1, 3, 7, 15, 16], we identified preoperative risk factors such as acidosis, ISS, age, GCS, and vital signs in a multivariable analysis. The mortality rate of DCL by year did not show a decreasing trend (Fig. 1). However, the mortality of all laparotomies showed a decreasing trend per year (p = 0.03). In particular, the RA-CUSUM curve showed a marked decrease and plateau, which indicates improved performance of DCL. While several previous studies in a non-trauma field used a RA-CUSUM analysis to evaluate surgical performance [10, 11, 17], RA-CUSUM has not been used for DCL or other trauma surgeries.

Similar to DCL, DCR has also emerged as a treatment to minimize resuscitation injury induced by fluid overload [2, 7]. Through DCR, a balanced ratio of FFP, platelet, and PRBC (1:1:1) in massive transfusions can mimic the whole blood components, resulting in more effective hemostasis [7, 18, 19]. DCR has been proven successful in combat casualty as well as civilian trauma victims [7]. In the TC period of the present study, the effort to achieve the 1:1:1 ratio of massive transfusion was accomplished, and the FFP/PRBC ratio was significantly increased. Despite this effort, the supplemental platelet from the blood bank in Korea is limited, and the platelets/PRBC ratio was not increased. However, in a most recent multicenter randomized control trial, there was no benefit for a higher ratio of platelets/PRBC [19]. As the trauma team was newly assembled in the TC period, more prompt surgery, angioembolization, and transfusions became more common. In the present study, the performance of fluid infusion

Table 2 Comparison of process (time values) and transfusion requirements between pre-trauma center (pre-TC) and trauma center (TC) periods

	Pre-TC ($N = 34$)	TC ($N = 85$)	p
Process (time values)			
Time from injury to admission, min	180 (119–180)	119 (60–180)	0.217
Operation time, min	99 (69–130)	80 (60–105)	0.022
Time from admission to OR, min	125 (92–191)	112 (65–151)	0.010
Time from admission to first treatment (operation or IVR)	119 (90–191)	99 (63–141)	0.004
Transfusion			
Massive transfusion (PRBC ≥ 10 unit within the first 24 h)	29 (85.3)	63 (74.1)	0.231
PRBC, unit (first 24 h)	18 (13–29)	15.5 (9.5–19)	0.034
FFP, unit (first 24 h)	10 (6–15)	11 (7–14)	0.832
Platelets, unit (first 24 h)	10 (2–20)	10 (6–17)	0.377
FFP/PRBC ratio (first 24 h)	0.56 (0.43–0.71)	0.72 (0.55–0.87)	0.006
Platelets/PRBC ratio (first 24 h)	0.58 (0.08–0.83)	0.61 (0.20–1.11)	0.604
Time from admission to first transfusion	70 (50–92)	52 (31–76)	0.009
30-Day mortality	17 (50.0)	33 (38.8)	0.264

Values are presented as *n* (%) or median (25th interquartile range to 75th interquartile range)

OR operation rood, *IVR* interventional radiology, *PRBC* packed red blood cell, *FFP* fresh frozen plasma

Table 3 Comparison of transfusion requirements in patients with massive transfusion (≥PRBC 10 units within the first 24 h) between pre-TC and TC periods

	pre-TC ($N = 29$)	TC ($N = 63$)	p
PRBC, unit (first 24 h)	21 (14–31)	17 (14–20.5)	0.070
FFP, unit (first 24 h)	11 (9–17)	12 (10–15)	0.607
Platelets, unit (first 24 h)	10 (8–20)	10 (8–19)	0.370
FFP/PRBC ratio (first 24 h)	0.56 (0.44–0.68)	0.72 (0.58–0.80)	0.004
Platelets/PRBC ratio (first 24 h)	0.59 (0.30–0.77)	0.60 (0.36–0.92)	0.787
Time from admission to first transfusion	70 (46–85)	48 (26.5–73.5)	0.008

Values are presented as median (25th interquartile range to 75th interquartile range)

PRBC packed red blood cell, *FFP* fresh frozen plasma

did not improve, even after increasing the infused plasma. While the use of crystalloids remained similar to the pre-TC period, the colloid use decreased significantly in the TC period. This may be attributed to the increased use of plasma and early transfusions. Some clinicians believe that the colloid fluid has a stronger volume effect than crystalloid. However, in a recent systematic review and meta-analysis of Cochrane collaboration [20], it was reported that colloid fluid (such as starches, dextrans, or albumin) did not show any benefits compared to the crystalloid fluid in terms of mortality or renal replacement.

In 2012, to establish a trauma system and reduce the preventable trauma death rate, the government of South Korea set up the support service for regional trauma centers that corresponds to level 1 trauma centers in the USA [8]. Seventeen regional trauma centers were selected and supported financially under this support service. Of these 17 centers, 14 established and developed the buildings, human resources, and facilities. This government-led establishment of trauma centers is a very unique situation in contrast with other countries. The trauma center is a foundation of the regional trauma system. The most significant improvement in the treatment of trauma patients was related to the development of a trauma system including trauma center maturity in the USA [21–23]. Owing to a short history of trauma centers in South Korea, the systemic maturity is still poor and the surgeon's experience of DCL is also insufficient. Recently, several previous studies in Korea reported improved outcomes of pelvic fracture, massive transfusion, and pre-peritoneal

Table 4 Univariate and multivariable analysis of preoperative risk factors for 30-day mortality

Variables	Univariate analysis			Multivariable analysis		
	COR	95% CI	*p*	AOR	95% CI	*p*
Penetrating injury (vs. blunt)	0.426	0.109–1.660	0.219			
Male sex (vs. female)	0.494	0.216–1.132	0.095			
First laboratory findings on admission						
Base excess	0.890	0.837–0.947	<0.001			
pH of ABGA (1 unit = 0.001)	0.995	0.993–0.998	<0.001	0.994	0.991–0.998	0.002
Hematocrit	0.952	0.903–1.002	0.061			
Preoperative CPR (vs. no CPR preoperatively)	13.028	2.804–60.524	0.001			
Injury severity score	1.037	0.997–1.078	0.067	1.081	1.023–1.142	0.006
Age, years	1.022	1.001–1.043	0.039	1.056	1.022–1.091	0.001
Intubated before admission	4.583	1.365–15.390	0.014			
Best motor score of GCS	0.617	0.498–0.763	<0.001	0.732	0.562–0.954	0.021
Initial systolic blood pressure, mm Hg	0.990	0.981–0.999	0.036	1.017	1.001–1.034	0.036
Initial pulse rate						
61–120 beat/min (reference)						
> 120 beat/min	1.325	0.455–3.859	0.606	1.311	0.266–6.476	0.739
31–60 beat/min	1.262	0.199–8.000	0.805	0.777	0.074–8.142	0.833
0–30 beat/min	8.202	2.156–31.209	0.002	19.561	2.107–181.623	0.009
Body temperature °C	0.504	0.199–1.281	0.150			
Preoperative inotropic drugs	1.448	0.683–3.073	0.335			

COR crude odds ratio, *AOR* adjusted odds ratio, *CI* confidence interval, *ABGA* arterial blood gas analysis, *CPR* cardiopulmonary resuscitation, *GCS* Glasgow Coma Scale

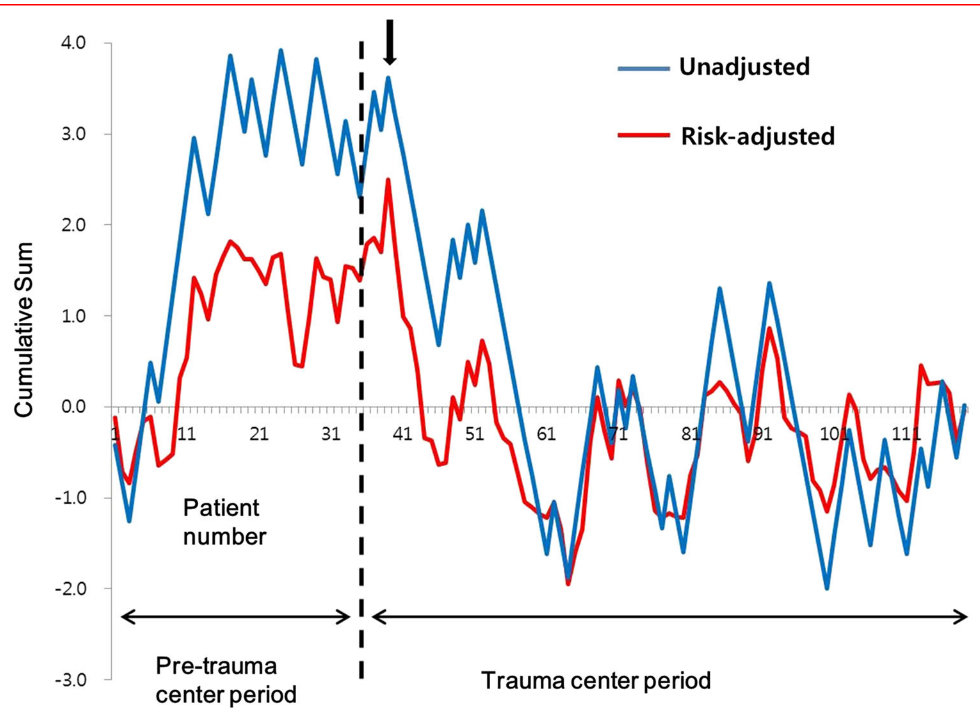

Fig. 2 Cumulative sum analysis (CUSUM) of 30-day mortality of damage control laparotomy. Blue line denotes unadjusted CUSUM. Red line denotes risk-adjusted CUSUM. The dotted line denotes the time of implementation of trauma center. At the 39th patient (arrows), a downward inflection was observed in both unadjusted and risk-adjusted CUSUM

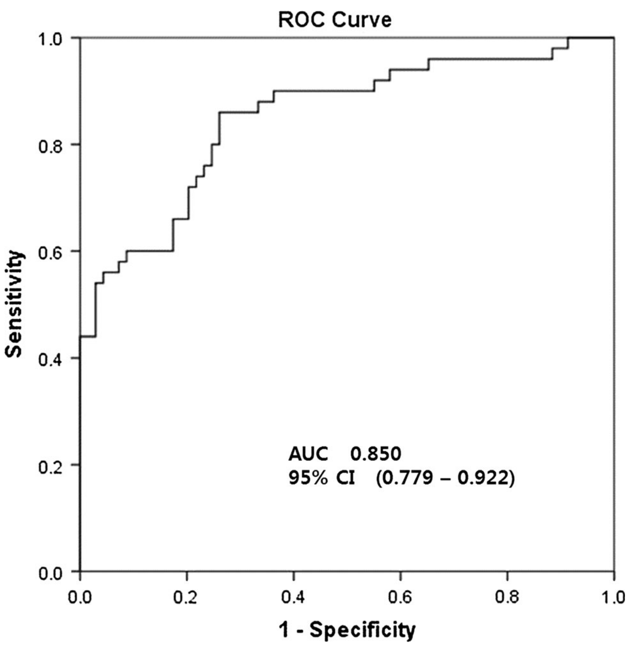

Fig. 3 Predictive performance of logistic regression model. ROC receiver operating characteristics; *AUC* area under curve, *CI* confidence interval

pelvic packing after the implementation of trauma centers [24, 25].

This is the first study using RA-CUSUM, which is an appropriate statistical tool to evaluate the surgical performance of DCL in terms of mortality. Furthermore, this is the first study addressing DCL after the government-led implementation of trauma centers in South Korea. We found that the implementation of trauma centers had a big impact on the quality improvement of treatment such as transfusions, processing times, and operations. Above all, the introduction of trauma surgeons is the biggest change. After the implementation of a trauma center, DCR and damage control surgeries began in earnest by trauma surgeons who have been dedicated to the trauma field. Moreover, dedicated facilities of the trauma center such as trauma bay, operating room, angiography suite, and intensive care units contributed to prompt resuscitation with hemostasis. These changes may have implications for the surgical performance of DCL.

Our study has several limitations. One of them is the retrospective nature of the study. However, no randomized control trial regarding DCL exists. The single cohort nature and small sample size of the study are also crucial limitations, and the analysis containing nested and larger cohorts is needed. The most important limitation is the various surgeons' skill level and experience. This may interfere with the consistency of quality of operation.

In conclusion, more prompt intervention and DCR could be achieved after the implementation of trauma centers, which is supported by the government. We believe that dedicated facilities, equipment, and manpower enabled this change. Moreover, by the RA-CUSUM analysis, we identified that risk-adjusted mortality of DCL was improved. This may be attributed to efforts of trauma surgeons and the new trauma system. Although a larger national cohort and prospective study is still necessary, we suggest that the support service for a regional trauma center in Korea could help to improve the outcomes of DCL for major trauma patients.

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Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interest.

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