DANISH MEDICAL JOURNAL

Original Article

Dan Med J 2022;69(6):A11210876

Adherence to and outcomes of bundle care in major abdominal emergency surgery

Rune M. Trangbaek[1], Jakob Burcharth[2] & Ismail Gögenur[2]

1) Department of Surgery, Slagelse Hospital, 2) Department of Surgery, Zealand University Hospital Koege, Denmark

Dan Med J 2022;69(6):A11210876

ABSTRACT

Introduction. Care bundles to improve post-operative outcomes after major abdominal emergency surgery have proven to be effective. This study investigated the correlation between adherence to protocol and post-operative outcomes after implementing perioperative bundle care at a single hospital.

Methods. This was a retrospective cohort study. Data were collected from 2018 to 2019. Patients undergoing surgery due to major emergency abdominal pathophysiology were included. The care bundle covered the pre-, intra- and post-operative course and included 12 elements. High adherence was defined as the completion of 70% of the elements. We used the Clavien-Dindo Classification and the Comprehensive Complication Index to evaluate post-operative complications.

Results. A total of 120 patients were included. High adherence was obtained in 54% of the patients. We found no difference in post-operative mortality or complications when comparing high adherence with low adherence. However, cases with high protocol adherence had a longer length of stay.

Conclusions. We found no difference in mortality or complications. Patients with a high adherence had a longer hospital stay.

Funding. none

Trial registration. not relevant.

Strategies for optimising the course of major emergency abdominal surgery have been evaluated with varying results. Single-centre studies have shown promising results with lowered mortality rates after using a structured care bundle [1, 2]. In contrast, an extensive multi-centre study failed to replicate those findings [3, 4]. Care bundles aim to improve outcomes by implementing several actions simultaneously, but only the cumulative effect is measured. Each action may not provide a measurable effect on its own, but in combination with other interventions, the collective effect leads to a superior outcome. Analysing the impact of individual elements in bundle care is challenging, and omitting either of them to investigate their isolated effect may be unethical. To gain insight into the implementation and thereby the effect, one can analyse adherence to bundle elements [4, 5].

Implementation rates in bundle care – and their correlation with clinical outcomes – have been investigated in the elective surgical setting such as enhanced recovery after surgery (ERAS) [6-10]. This showed that increased adherence to protocol correlated with improved outcomes.

So far, no studies have examined the association between adherence to protocol and clinical outcomes in an emergency surgical setting. Therefore, this study aimed to investigate if increased adherence to protocol in major emergency abdominal surgery influenced post-operative complications and mortality.

METHODS

This was a retrospective cohort study. We initiated bundle care for patients undergoing major abdominal emergency surgery coined the "Abdominal Surgery Acute Protocol". The bundle included 12 clinical and administrative elements (**Table 1**).

TABLE 1 Protocol content.

	Course		
	preoperative	**intraoperative**	**post-operative**
Clinical elements	IV antibiotics Decompression tube CT scan within 1 h Surgery within 6 h	Thoracic epidural	Physiotherapy
Administrative elements	*Project folder*		
	4-page leaflet including timestamps and checklists for preoperative, intraoperative and post-operative courses		
	Entry note template	*Surgery note template*	*Ward arrival note template*
	Contains objective findings and patient history, including ASA score and performance score	Contains the type of surgery, pathology, operating techniques and post-operative plan	Contains post-operative details about the patient, including decompression tube, indwelling catheter, epidural, pain and fluid management
	Booking note template		*Rounds note template*
	Includes information about the upcoming surgery and patient information, ASA score and performance score		Includes mobilisation, pain, intestinal function, fluid management, infections, blood tests, antibiotics, objective assessment and treatment plan

ASA = American Society of Anesthesiologists; IV = intravenous.

Preoperative clinical elements

Single-dose antibiotics were administered on suspicion of any condition that would require major abdominal emergency surgery [11]. A nasogastric tube was inserted to avoid further intestinal load and prevent vomiting [12]. A fast-track computed tomography (CT) was concluded within one hour after it was requested. If the patient needed emergency surgery, this was scheduled as the next possible procedure with latest start-up within six hours from the decision to operate. If start-up was anticipated to take more than six hours, an additional operating room was opened.

Intraoperative clinical elements

Patients were administered a thoracic epidural unless contraindicated. Contraindications were the use of anticoagulants or circulatory instability.

Post-operative clinical elements

At the end of the surgery, the patients were stratified as being at either major risk or minor risk of death. The patient was considered to have a major risk if he or she obtained a surgical Apgar (appearance, pulse, grimace, activity and respiration) score ≤ 4 or had an American Society of Anesthesiologists (ASA) score > 2 [13, 14]. The surgical Apgar score was calculated using intraoperative measurements of blood loss, mean arterial pressure and heart rate. The post-operative destination for those assessed to be at major risk was the intensive or intermediate care unit for 24 hours. Patients who were considered to be at minor risk would first go to the recovery room for observation and then to the surgical ward. Physiotherapy, including mobilisation, was performed as soon as possible.

We used a standardised morphine-sparring regime in which morphine was given as needed only. Additional analgesics consisted of paracetamol (1 g, four times a day) and ibuprofen (600 mg, three times a day) unless contraindicated. If patients were not administered an epidural, they were initially allowed prolonged release tramadol 50 mg twice a day.

Administrative elements

Electronic journal-entry templates were used to maintain uniformity and help the staff remember the elements at any stage. The "Entry note" included history, clinical examination, ASA score, performance score, blood tests and suspected diagnosis. The surgical "Booking Note" included the type of surgery, suspected pathology and risk of conversion from laparoscopic to open surgery. The "Surgery Note" included a description of the procedure and a post-operative plan. The "Ward Arrival Note" contained post-operative care details for the nursing staff. The "Rounds Note" included mobilisation, pain, intestinal function, resuscitation, blood tests, antibiotics, clinical assessment and treatment plan. A four-page project folder was used for documentation when the patient was enrolled in the protocol. It covered all stages with timestamps and checklists.

Implementation

Before the bundle was initiated, a campaign was implemented for involved staff wherein all care bundle elements were explained and background information was provided. Staff in the emergency ward attended two educational sessions before the implementation. The surgeons had multiple sessions where they were provided with examples of the electronic templates. Radiologists and physiotherapists were also given a presentation of the bundle. All doctors in the Emergency, Surgical and Anaesthesiology Departments were given action cards. After the implementation, both doctors and nurses attended follow-up sessions to ensure adherence and allow new staff members to obtain information. Furthermore, the surgeons were reminded of the bundle daily during the first month.

Setting

Data were collected from June 2018 to June 2019 from a single hospital. Follow-up time for mortality was one year; for post-operative complications, 30 days.

Participants

Patients were included if they underwent emergency laparotomy or laparoscopy. The following conditions were included: mechanical bowel obstruction, intestinal ischaemia, gastrointestinal perforation, intra-abdominal abscess and bleeding. The exclusion criteria were surgery due to trauma, appendicitis and cholecystitis. Patients were excluded from analysis if they had been transferred from another ward or hospital. Furthermore, emergency re-operations from planned surgery were also excluded.

Variables

The primary outcome was possible associations between adherence to bundle elements and post-operative outcomes. The secondary outcome was adherence rates of bundle elements. We defined high adherence as completion of at least 70% of the elements within one case. Implementation of an element was considered a success if it was completed in 70% of the patients. This approach was inspired by prior research on protocol adherence in an ERAS setting [6, 8]. As there were 12 elements, each patient needed to have undergone at least nine elements to reach high adherence. Complications were analysed using the Comprehensive Complication Index (CCI) [15]. The CCI summarises all post-operative complications into a single score for each patient, thereby making it possible to quantify several complications. We also analysed complications with a Clavien–Dindo score > 2 [16]. Finally, we listed complications as either medical (pulmonary, cardiac, neurological or nephrological) or surgical (surgical site infections, wound dehiscence, bleeding or mechanical bowel obstruction).

Data sources

All data were collected from the electronic patient files.

Bias

We had no loss to follow-up. There were no missing data from adherence to protocol elements.

Quantitative variables

Age, duration of surgery and other continuous variables were stated as median and interquartile range (IQR). Based on BMI, patients were grouped into underweight (< 18.5 kg/m^2), normal weight (18.5-24.9 kg/m^2) or overweight (≥ 25 kg/m^2). The Charlson Comorbidity Index score was grouped into mild (0-2), moderate (3-5) or severe (> 5). The CCI was calculated from Clavien–Dindo-graded complications and remained a continuous variable for analysis [15]. All other variables were stated as counts and frequency.

Approvals: No patient consent was needed for this type of study, nor was approval by the ethics board. The study was approved by the Danish Data Protection Agency [17].

Statistical methods

R studio v. 1.3.1093 was used for all statistical analyses. For binary analyses, we used the χ^2-test for categorical variables and the Kruskal-Wallis test for continuous variables. For analysing how adherence influenced CCI, we performed an unadjusted linear regression analysis. We used zero (low adherence) as a reference. Results from linear regression were stated as a decrease or increase in CCI scores with 95% confidence intervals (CI). Missing values are mentioned below tables. There were no missing data in the variables used for analysis. Statistical significance was set to p = 0.05.

Trial registration: not relevant.

RESULTS

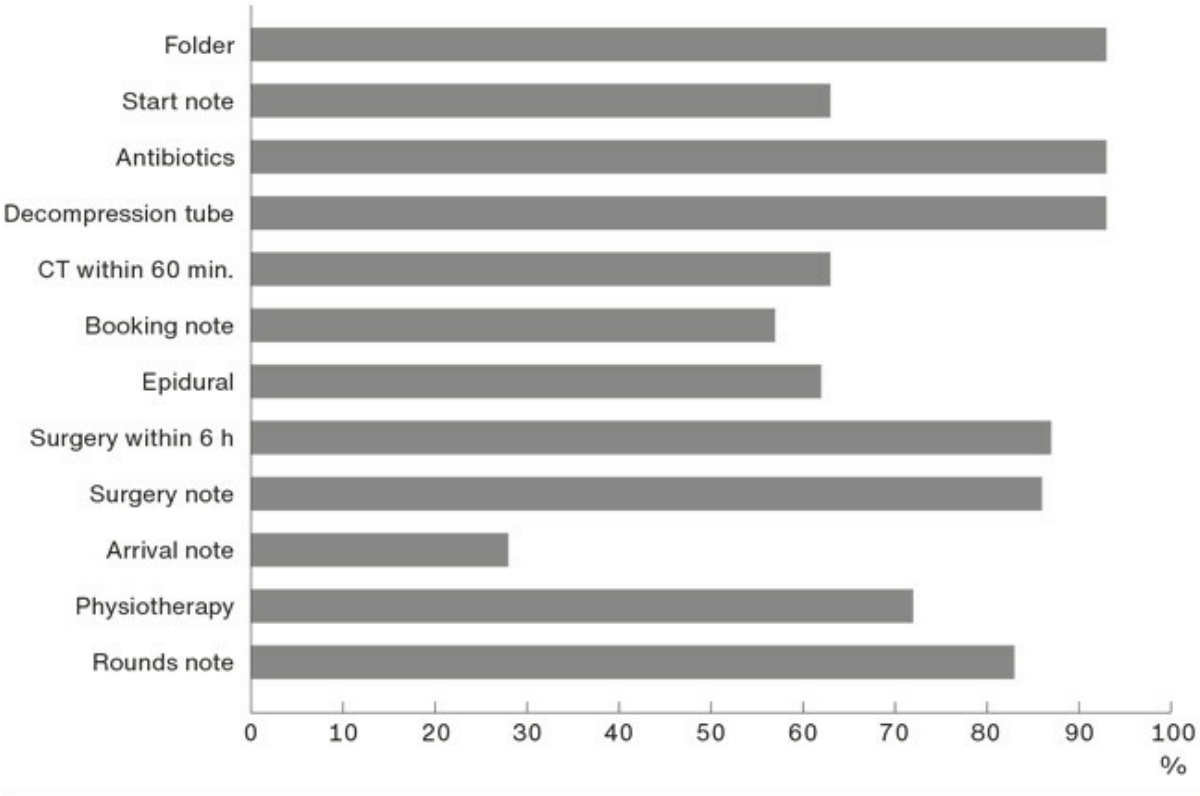
A total of 181 patients were treated according to the bundle. Based on eligibility criteria, we excluded 61 patients, which led to 120 patients finally being available for analysis. Excluded patients included 15 patients who underwent re-operation from elective surgery and 46 patients who were transferred from another hospital. The median age of the population was 71 years (IQR: 58-78). The most frequent surgical diagnosis was mechanical bowel obstruction followed by gastrointestinal perforation. Cases with a low adherence had a lower Charlson Comorbidity Index and the duration of surgery was shorter. Further description of the cohort is presented in **Table 2**. Out of the 12 bundle elements, seven (58%) were defined as a success with completion in ≥ 70% of the cases. **Figure 1** shows each element of the bundle and the adherence distribution. Five elements did not reach a 70% completion rate, of which three were made up of entry-note templates. The least successful element was the arrival note template. A CT was performed within one hour in 63% of the cases. The median waiting time for a CT was 43 min (IQR: 25-86). A thoracic epidural was administered in 62% of the cases who underwent laparotomy and were eligible for an epidural.

TABLE 2 Characteristics of 120 patients.

	Low adherence (n = 55)	High adherence (n = 65)	Total (N = 120)	p-value
Age, yrs, median (IQR)	69 (57-74)	72 (59-80)	71 (58-78)	0.141
Sex: male, n (%)	24 (43.6)	27 (41.5)	51 (42.5)	0.213
Smoker, n (%)[a]	15 (27.8)	7 (12.1)	22 (19.6)	0.963
Diabetes, n (%)[b]	7 (13.0)	10 (15.4)	17 (14.3)	0.910
BMI, n (%)[c]				0.810
Underweight: < 14.5 kg/m²	4 (7.5)	3 (4.7)	7 (6.0)	
Normal weight: 14.5-24.9 kg/m²	25 (47.2)	31 (48.4)	56 (47.9)	
Overweight: > 25 kg/m²	24 (45.3)	30 (46.9)	54 (46.2)	
Anticoagulants, n (%)[d]	20 (37.0)	14 (22.2)	34 (29.1)	0.119
Charlson Comorbidity Index score, n (%)				0.037
Mild: 0-2	20 (36.4)	12 (18.5)	32 (26.7)	
Moderate: 3-5	21 (38.2)	39 (60.0)	60 (50.0)	
Severe: > 5	14 (25.5)	14 (21.5)	28 (23.3)	
Surgical diagnosis, n (%)				-
Mechanical bowel obstruction	36 (65.5)	43 (66.2)	79 (65.8)	
Gastrointestinal perforation	14 (25.5)	13 (20.0)	27 (22.5)	
Perforated ulcer	1 (1.8)	8 (12.3)	9 (7.5)	
Intestinal ischaemia	3 (5.5)	0	3 (2.5)	
Intra-abdominal bleeding	1 (1.8)	1 (1.5)	2 (1.7)	
Duration of surgery, min., median (IQR)	102 (57.5-152)	123 (83-179)	113 (68.2-170.5)	0.050

IQR = interquartile range.
a) 8 missing.
b) 1 missing.
c) 3 missing.
d) 3 missing.

FIGURE 1 Completion rate of each element. Adherence rates are stated in chronological order. The rate of epidural was from eligible patients who underwent open surgery.



Among the 120 patients, 65 (54%) were defined as high-adherence patients. No statistically significant difference was observed in mortality rates. However, cases with a high adherence had a longer median length of stay (**Table 3**). Finally, unadjusted linear regression revealed no difference in CCI score between patients with a high adherence and a low adherence (0.787 points; 95% CI: –9.145-10.718)

TABLE 3 Binary analysis: X^2-test on complications and mortalities.

	High adherence[a]		
	no (n = 55)	yes (n = 65)	p-value
CCI score[b], median (IQR)[c]	8.7 (0-33.7)	8.7 (0-33.7)	0.645
Medical complication, n (%)	21 (38.2)	35 (53.8)	0.126
Surgical complication, n (%)	10 (18.2)	10 (15.4)	0.870
Clavien-Dindo score > 2, n (%)	14 (25.5)	27 (26.2)	1
ICU admission, n (%)	1 (1.8)	4 (6.2)	0.468
30-day mortality, n (%)	5 (9.1)	3 (4.6)	0.540
90-day mortality, n (%)	11 (20)	5 (7.7)	0.088
180-day mortality, n (%)	11 (20)	9 (13.8)	0.512
1-year mortality, n (%)	15 (27.3)	11 (16.9)	0.251
Length of stay, days, median (IQR)[c]	6 (3-11)	8 (5-14)	0.037

CCI = Comprehensive Complication Index; IQR = interquartile range.
a) ≥ 70% of the elements in the bundle completed.
b) Summarises all post-operative complications from a patient into 1 score: 0-100 [15].
c) Analysed with the Kruskal-Wallis test.

DISCUSSION

Patients with a high adherence had a longer length of stay but no statistically significant difference in mortality or complications. More than half of the elements in the bundle were defined as successful.

As previously described, we defined high adherence as completion of at least 70% of the elements within one case [6]. To obtain better adherence, we conduced teaching sessions with both nurses and doctors. Every bundle element was explained and all administrative parts were exemplified in detail. However, we could have performed better on maintaining attentiveness and informing new staff. As the study was conducted in a teaching hospital, staff turnover was considerable and new staff were not always fully informed about the bundle.

Length of stay was longer in high-adherence cases. The same cases had a longer duration of surgery, which may indicate difficult surgical conditions that may have influenced the post-operative course. The longer stay may also potentially be attributed to confounding by indication as described in the Limitations section. Finally, we raise the question if length of stay is an appropriate outcome when optimising major emergency surgery to increase survival.

Three out of the five unsuccessful elements were electronic templates. The ward arrival note was the least successful element in the protocol. A possible reason was that the ward arrival note was recorded by nurses who had never used the journaling part of the system. Nurses received instructions on how to record a note into the system, but no formal training on this was provided.

Large-scale implementation of bundle care was attempted at 93 hospitals in the EPOCH trial [3, 4]. Similar to what we observed, many sites in the EPOCH trial wished they had a more comprehensive engagement. Before our implementation, we held meetings with the Departments of Radiology, Emergency, Anaesthesia and Physiotherapy. The meetings focused on ensuring a common understanding of and establishing support for the protocol.

A study in elective surgery, but similar to the present study, found that increasing adherence was statistically associated with a lower rate of post-operative complications [6]. However, patients undergoing emergency surgery and those undergoing elective surgery are not comparable. Major emergency surgery requires resuscitation and urgency, and the patients are often in physiological distress due to dehydration, fasting and sepsis. Adhering to a protocol is probably more challenging in emergency surgery than in an elective setting. A related study analysed the adherence to bundle care in emergency surgery and found a ≥ 70% adherence to bundle elements [5]. However, this study did not correlate the adherence rate to clinical outcomes.

Future studies on adherence in an emergency setting should be performed with biochemical markers and should include more patients in order to investigate their physiological and immunological response. Furthermore, using a success criterion for high adherence is a flexible and predefined tool and should be implemented in future research. As described earlier, omitting certain elements of a bundle may be unethical. However, it may be possible to construct a randomised controlled trial to investigate the effect of the administrative elements on post-operative outcomes.

This study had several limitations. We detected no statistically significant difference in mortality, which may potentially be due to the study size. A risk of confounding by indication exists as patients with poorer physiological conditions may have received more attention, thereby obtaining a greater adherence to protocol and contributing to a longer length of stay.

CONCLUSIONS

High adherence to bundle elements increased post-operative length of stay, but did not change mortality rates or complications. For future research, we should consider if length of stay is a meaningful outcome for emergency surgery. Creating a wider sense of responsibility among staff and paying special attention to their behavioural changes may possibly have increased adherence to the protocol.

Correspondence *Rune M. Trangbaek*. E-mail: runemt@gmail.com

Accepted 31 March 2022

Conflicts of interest none. Disclosure forms provided by the authors are available with the article at ugeskriftet.dk/dmj

Cite this as Dan Med J 2022;69(6):A11210876

REFERENCES

1. Tengberg LT, Bay-Nielsen M, Bisgaard T et al. Multidisciplinary perioperative protocol in patients undergoing acute high-risk abdominal surgery. Br J Surg. 2017;104(4):463-71.
2. Huddart S, Peden CJ, Swart M et al. Use of a pathway quality improvement care bundle to reduce mortality after emergency laparotomy. Br J Surg. 2015;102(1):57-66.
3. Peden CJ, Stephens T, Martin G et al. Effectiveness of a national quality improvement programme to improve survival after emergency abdominal surgery (EPOCH): a stepped-wedge cluster-randomised trial. Lancet. 2019;393(10187):2213-1.

4. Peden CJ, Stephens T, Martin G et al. A national quality improvement programme to improve survival after emergency abdominal surgery: the EPOCH stepped-wedge cluster RCT. Health Services and Delivery Research. 2019;7.
5. Burcharth J, Abdulhady L, Danker J et al. Implementation of a multidisciplinary perioperative protocol in major emergency abdominal surgery. Eur J Trauma Emerg Surg. 2021;47(2):467-77.
6. Gustafsson UO, Hausel J, Thorell A et al. Adherence to the enhanced recovery after surgery protocol and outcomes after colorectal cancer surgery. Arch Surg. 2011;146(5):571–7.
7. P&;dziwiatr M, Kisialeuski M, Wierdak M et al. Early implementation of Enhanced Recovery After Surgery (ERAS®) protocol - compliance improves outcomes: a prospective cohort study. Int J Surg. 2015;21:75-81.
8. Pisarska M, P&;dziwiatr M, Ma&;czak P et al. Do we really need the full compliance with ERAS protocol in laparoscopic colorectal surgery? A prospective cohort study. Int J Surg. 2016;36(pt A):377-82.
9. Currie A, Burch J, Jenkins JT et al. The impact of enhanced recovery protocol compliance on elective colorectal cancer resection: results from an international registry. Ann Surg. 2015;261(6):1153-9.
10. Ahmed J, Khan S, Lim M et al. Enhanced recovery after surgery protocols - compliance and variations in practice during routine colorectal surgery. Colorectal Dis. 2012;14(9):1045-51.
11. Levy MM, Evans LE, Rhodes A. The surviving sepsis campaign bundle: 2018 update. Crit Care Med. 2018;46(6):997-1000.
12. Salem MR, Khorasani A, Saatee S et al. Gastric tubes and airway management in patients at risk of aspiration: history, current concepts, and proposal of an algorithm. Anesth Analg. 2014;118(3):569-79.
13. Cihoric M, Tengberg LT, Bay-Nielsen M et al. Prediction of outcome after emergency high-risk intra-abdominal surgery using the surgical apgar score. Anesth Analg. 2016;123(6):1516-21.
14. Sobol JB, Gershengorn HB, Wunsch H et al. The surgical Apgar score is strongly associated with intensive care unit admission after high-risk intraabdominal surgery. Anesth Analg. 2013;117(2):438-46.
15. Slankamenac K, Graf R, Barkun J et al. The comprehensive complication index: a novel continuous scale to measure surgical morbidity. Ann Surg. 2013;258(1):1-7.
16. Dindo D, Demartines N, Clavien P-A. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004;240(2):205-13.
17. Datatilsynet. www.datatilsynet.dk (1 Dec 2021).