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## SURGERY | RESEARCH ARTICLE

# Adverse events identified by Global Trigger Tool in 245 patients with colon cancer in a well-defined population

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**Abstract:** *Purpose:* To report the rate, the type and the preventability of adverse events in patients with colon cancer. *Materials and methods:* In this retrospective population-based study conducted at one university hospital and six district hospitals from a region with one million inhabitants during an 8-month period 245 patients were diagnosed with colon cancer. The medical records were reviewed with the Global Trigger Tool method and the adverse events categorized as *E* (harm requiring some treatment), *F* (prolonged hospital stay), *G* (permanent disability), *H* (life saving measures performed in the intensive care unit), *I* (mortality associated with harm). Degree of preventability was evaluated. *Results:* Adverse events ( $n = 112$ ) were reported in 35.9% of the patients ( $n = 88$ ). They were more common after urgent than after elective admittance (45.3 vs. 31.8%). Category *E* was registered in 11.0%, *F* in 18.8%, and *I* in 6.1% (53.3% after urgent and 2.4% after elective admittance). Preventable or possibly preventable adverse events were judged to occur in 88.9% in the *E* group, in 97.8% in the *F* group, and in 53.3% in the *I* group. Adverse events associated with the surgical procedure dominated. There was a wide range of various types of adverse events but manifestations from the abdominal wall dominated. *Conclusion:* Adverse events were reported in one third of the patients. The majority of the adverse events in the whole cohort, and almost half of the patients who died postoperatively were assessed as possibly preventable or preventable.

### ABOUT THE AUTHOR

Professor emeritus of surgery with a special interest in colorectal surgery (inflammatory bowel disease, anorectal function, colorectal cancer). During the latest years the main interest has been various aspects of Patient Safety.

### PUBLIC INTEREST STATEMENT

There is a growing interest in patient safety in medicine. Unexpected/unwanted events during medical care are usually reported as complications but from the patients' perspective they are experienced as adverse events—not preventable or preventable. In this article the outcome is presented of 245 patients treated for large bowel cancer during an 8-month period in a defined population of one million inhabitants in Sweden. By using an established method (Global Trigger Tool) for retrospectively reviewing medical records we could identify adverse events in one third of the patients—significantly more after urgent than after planned admittance. Most common were adverse events of the abdominal wall associated with the surgical incision. The majority of the adverse events was judged as possibly preventable or preventable. Various suggestions are made to avoid adverse events, e.g. to perform minimal invasive instead of open surgery.

**Subjects:** Colorectal Surgery; Gastrointestinal Oncology; Medicine; Oncology; Surgery

**Keywords:** colon cancer; Global Trigger Tool; surgery; adverse events; preventability

### 1. Introduction

Colorectal cancer surgery is a major contributor to adverse events that lead to harm or death. Traditionally the adverse events are reported as complications in the medical literature but there is a trend to reflect also the consequences e.g. by using the Clavien-Dindo classification (Clavien et al., 2009; Dindo, Demartines, & Clavien, 2004). Various methods have been used to identify medical adverse events. The Global Trigger Tool (GTT) has been widely used for several years (Classen, Lloyd, Provost, Griffin, & Resar, 2008; Griffin & Resar, 2009) and was introduced in Sweden in 2007. It aims to enable comparisons and assessments of implemented patient safety measures and to identify target areas for improvements. In the majority of reports randomly selected medical records have been reviewed every month at hospital level (Good, Saldana, Gilder, Nicewander, & Kennerly, 2011; Sharek, Parry, Goldman, et al., 2010) but some reports have been published at department level—also in Sweden (Sjödahl, Hultcrantz, Melander, & Juhlin, 2010; Unbeck, Muren, & Lillkrona, 2008). In addition, GTT can also be used to review deceased patients (Nilsson, Juhlin, Krook, Sjödahl, & Rutberg, 2009), or special fields within the medical area. A colon cancer project in the southeast region of Sweden initiated by the Swedish government focused on the patients' perspective of the care from diagnosis to curative or palliative treatment, and to rehabilitation. The present study is a separate part and these patients were not included in other reports of the national project. To evaluate adverse events/harm incidents in that patient group we have reviewed the records of all patients diagnosed with colon cancer in the southeast region of Sweden during an eight-month period. The aim of this retrospective population-based study was to identify and describe all adverse events that were detected by GTT during a defined time period, to evaluate the degree of preventability, and to identify areas requiring improvement.

### 2. Materials and methods

The southeast region of Sweden has one million inhabitants. Colon cancer is managed by seven hospitals. The Regional Cancer Centre is responsible for the registration at diagnosis and at follow-ups of all colon cancers in the region. A national registry of all cancer diagnoses served as a comparison for complete number of patients. Some 99% of all patients diagnosed with colon cancer were included in this population-based study. The remaining two patients were not included due to missing information. Totally 260 medical records were reviewed but 15 were excluded (rectal cancer, rectosigmoid cancer, cancer of the appendix). The colon cancer was located to various parts of the colon and consequently different surgical methods were used as open right or left hemicolectomy, sigmoid resection, or subtotal colectomy. Two patients had neoadjuvant treatment before synchronous operation of the primary tumor and liver metastases, and adjuvant cytostatic drugs were used in stage III disease provided the general condition of the patient permitted such treatment.

Twelve well-trained nurses with at least two years of experience with the GTT method reviewed the medical records of all patients admitted because of colon cancer from 1 September 2011 to 30 April 2012. The scoring was performed at discharge and a standardized protocol was used comprising 46 triggers (Table 1). The method was slightly modified as only one of the nurses reviewed each record, presented the triggers and suggested an adverse event to a surgeon who has a substantial experience of colorectal surgery and is well educated in patient safety. He made all the judgments together with the nurse and sometimes together with other surgeons at his department. The inter-individual variation in scoring among the nurses was not investigated. Accepted categories of harm according to NCC MERP (National Coordinating Council for Medication Error Reporting and Prevention) were used. Category E means harm which required some treatment but did not prolong the hospital stay, category F reflects a prolonged hospital stay or an unplanned readmission, G permanent disability, H life saving measures performed in the intensive care unit, and category I means mortality associated with harm (Classen et al., 2008; Griffin & Resar, 2009). Prolonged hospital stay was

**Table 1. Triggers (n = 46) used at the reviews**

<b>Cares module triggers</b>	
1	Transfusion of blood
2	Hemoglobin fall
3	In-hospital stroke
4	Cardiac arrest
5	Dialysis
6	Positive blood culture
7	Deep vein thrombosis or emboli
8	Falls
9	Pressure ulcers
10	Readmission within 30 days
11	Healthcare-associated infections
12	Transfer to higher level of care
13	Documentation of mistakes
14	Other
<b>Medication module triggers</b>	
15	<i>Clostridium difficile</i> positive stool
16	APT-time greater than 100 s
17	International normalized ratio (INR) greater than 6
18	Glucose less than 3 mmol/l
19	Serum creatinine two times over baseline
20	Vitamin K/factor concentrate
21	Antihistamine
22	Flumazenil
23	Naloxone
24	Anti-emetics
25	Over sedation/hypotension
26	Abrupt medication stop
<b>Surgical module triggers</b>	
27	Reoperation
28	Change in procedure
29	Unplanned postoperative intensive care
30	Intubation/reintubation/CPAP/BiPap
31	X-ray intra-operatively or in postoperative care unit
32	Intra- or postoperative death
33	Mechanical ventilation more than 24 h
34	Intraoperative administration of epinephrine, norepinephrine, naloxone, flumazenil
35	Postoperative increase in troponin levels
36	Change of anesthetic during surgery
37	Consult requested in the postoperative unit
38	Postoperative complication
39	Unsuspected pathology findings
40	Insertion of arterial or central line during surgery
41	Intra-operative time greater than 6 h
42	Removal/injury or repair of organ during surgery

(Continued)

**Table 1. (Continued)**

Intensive care module triggers	
43	Pneumonia
44	Readmission to ICU
45	Procedures in ICU
46	Intubation/reintubation

defined as more than 7 days after elective admission and more than 10 days after urgent admission. In addition to the original GTT the degree of preventability was evaluated according the Swedish categorization (Estling, 2013): 1 not preventable, 2 possibly not preventable, 3 possibly preventable, 4 preventable. In patients with more than one adverse event the worst adverse event was reported regarding preventability (F and I).

**2.1. Statistical methods**

The Fisher exact test was used to determine if there were any statistically significant differences between the various groups. For the analyses  $p < 0.05$  was regarded as statistically significant. Statistical software IBM SPSS V.21 was used for the statistical analyses.

**2.2. Ethics**

This study was part of a quality control and the study design was approved by the regional health care authority (Registration number RSN 2011–6).

**3. Results**

Altogether 245 patients were admitted due to colon cancer and all records were reviewed. The number of patients differed from 15 to 54 among the hospitals. Some 170 patients (69.4%) had elective admittance with a range of 10 to 36 patients among the hospitals. Urgent admittance occurred in 75 patients (30.6%), the number varied from 3 to 23 patients in different hospitals. Removal of the primary tumor was done in 213 patients (86.9%), stoma or ileotransverseostomy in 4 patients, and 28 patients (urgent admittance 15, elective admittance 13) were not operated on (11.4%) due to advanced disease and poor general condition, or unwillingness to be operated. The tumor stages are shown in Table 2. Two of the 34 patients with stage IV disease received neoadjuvant chemotherapy.

Some kind of adverse event was found in 88 patients (35.9%) but there was a substantial difference between the 7 hospitals (20–50%). Altogether 112 adverse events were detected (1.3/patient). After urgent admittance 34 patients (45.3%) experienced an adverse event and after elective admittance 54 patients (31.8%), which is a statistically significant difference ( $p = 0.04$ ). There were no obvious differences in the pattern of adverse events between the hospitals except that gastric retention and fluid overload was less common when the ERAS concept was used.

**Table 2. Tumour stage in 245 patients admitted for colon cancer**

Tumour stage	Urgent admittance, n (%)	Elective admittance, n (%)	Total, n (%)
I	1 (1)	17 (10)	18 (7)
II	30 (40)	76 (45)	106 (43)
III	21 (28)	57 (34)	78 (32)
IV	21 (28)	13 (8)	34 (14)
Unknown	2 (3)	7 (4)	9 (4)

Note: The TNM stage was unknown in 9 patients (3.7%) not undergoing bowel resection (biopsy only, radiologic diagnosis).

The categories of adverse event/harm according to NCC MERP are shown in Table 3. The category E was registered in 11.0%, and the category of F in 18.8%. There was no difference regarding category E and F after urgent or elective admittance ( $p > 0.05$ ). No categories of G or H were found.

The 30-day mortality (category I) was 6.1%. It was 14.7% after urgent admittance and 2.4% after elective admittance ( $p = 0.001$ ). The cause of death was cardiovascular or multiple organ failure. In the end of 2012 some 38 patients had died, 16 of them had stage IV disease, 12 had stage II, 6 had stage III, and 4 had unknown tumor stage.

Degree of preventability of the adverse events is shown in Table 4. There was no difference between urgent and elective admittance ( $p > 0.05$ ). The majority of the E category (88.9%) was assessed as possibly preventable or preventable, the corresponding figures for F and I were 97.8 and 53.3% respectively. Adverse events occurred in 5 out of 28 patients (17.9%) not being operated—three were judged to be possibly preventable or preventable. For those who were operated ( $n = 213$ ) an adverse event occurred in 40.0%, and was judged to be possibly preventable or preventable in 91.6%.

**Table 3. Categories of harm in 88 patients according to NCC MERP**

Type	Urgent (n = 34/75)	Elective (n = 54/170)	Total (n = 88/245)
E	10 (13)	17 (10)	27 (11)
F	13 (17)	33 (19)	46 (19)
G	0	0	0
H	0	0	0
I	11 (15)	4 (2)	15 (6)

Notes: Number of patients is shown (percentage within brackets). E reflects an adverse event that required treatment but did not result in prolonged hospital stay, F means a prolonged hospital stay (>7 days after elective surgery and >10 days after urgent admittance) due to the harm, G permanent handicap, H shows that acute life saving measures was demanding in the intensive care unit, I means mortality because of the harm. Adverse events occurred in 44% of patients after urgent admittance and in 32% after elective admittance.

**Table 4. Degree of preventability of adverse events related to category of harm, and urgent or elective admittance**

Category of harm (NCC MERP)	Degree of preventability (1–4)	Urgent admittance (n = 34)	Elective admittance (n = 54)	Total (n = 88)
E	1	2	1	3
	2	0	0	0
	3	6	13	19
	4	2	3	5
F	1	0	0	0
	2	0	1	1
	3	10	22	32
	4	3	10	13
G		0	0	0
H		0	0	0
I	1	2	1	3
	2	4	0	4
	3	3	3	6
	4	2	0	2

Notes: Not preventable: 1, possibly not preventable: 2, possibly preventable: 3, preventable: 4.

**Table 5. Classification of 112 adverse events in 88 out of 245 patients with colon cancer after urgent (*n* = 75) and elective (*n* = 170) admittance**

Type	Urgent	Elective	Total ( <i>n</i> = 245)
Wound infection	6 (8)	16 (9)	22 (9)
Fluid overload (gain in weight >3 kg)	5 (7)	8 (5)	13 (5)
Wound dehiscence	3 (4)	9 (5)	12 (5)
Hospital acquired pneumonia	8 (11)	3 (2)	11 (4)
Gastric retention (requiring gastric tube)	7 (10)	1 (1)	8 (3)
Anastomotic leakage	1 (1)	5 (3)	6 (2)
Postoperative bleeding	1 (1)	5 (3)	6 (2)
Intestinal obstruction	1 (1)	5 (3)	6 (2)
Injury to abdominal organ	2 (3)	3 (2)	5 (2)
Myocardial infarction	4 (5)	0	4 (2)
Stoma complication	3 (4)	1 (1)	4 (2)
Pulmonary embolism	2 (3)	1 (1)	3 (1)
Abdominal abscess	0	3 (2)	3 (1)
Enterocutaneous fistula	0	2 (1)	2 (1)
Miscellaneous	4 (5)	3 (2)	7 (3)

Note: The table shows the number of patients in each group (percentage within brackets).

The different types of adverse events are shown in Table 5. Harms associated with the surgical procedure dominated. Altogether wound infection and wound dehiscence occurred in 14% of the patients and fluid overload or gastric retention in 8%. Totally 10% had anastomotic leakage, postoperative bleeding, injury to an abdominal organ, intestinal obstruction, or complications from a stoma. There was no difference between the hospitals and no difference between urgent and elective admittance regarding various types of adverse events ( $p > 0.05$ ).

Stage IV at diagnosis of the colon cancer was reported in 34 patients, 21 (28%) after urgent admittance and 13 patients (8%) after elective admittance ( $p = 0.001$ ). Adverse events were reported in 12 of these patients (35.3%)—in 8 after urgent admittance and in 4 after elective admittance. There were no differences in preventability between urgent and elective admittance in stage IV patients ( $p > 0.05$ ). The type of adverse events did neither differ between stage IV patients and the whole cohort.

#### 4. Discussion

To the best of our knowledge this is the first report using the GTT-method in a population-based patient group with colon cancer. Open surgery was used during the study period but laparoscopic surgery has then gradually been introduced. Adverse events were detected in about one third of the patients including all tumor stages. There was a wide range of various types of adverse events but manifestations associated with the abdominal wall dominated (wound infection, wound rupture). As one could expect adverse events including postoperative mortality were more common in patients after urgent than after elective admittance.

The majority of the adverse events were judged as possibly preventable or preventable. Of the deceased patients about half had a possibly preventable or preventable adverse event associated with the outcome. Our intention regarding preventability is neither to accept nor to blame but to stimulate improvement work. Symptoms that are caused by an adverse event are the same irrespective of the preventability. The approach was that when there was a substantial chance (more than 50%) to avoid a certain adverse event it was assessed as possibly preventable. This may be hard to

accept e.g. for a surgeon who has done exactly the same procedures in a series of operations but consideration should then be taken to the patient's general condition or to use another type of operation or a staged operation. Preventable adverse events were associated with obvious mistakes.

The patient material comprised patients diagnosed with colon cancer during an eight-month period in the southeast region of Sweden with one million inhabitants. Specialized nurses reviewed the medical records of all patients. It has been reported that the assessment of adverse events could differ between different teams also when they were experienced in using the GTT-method (Schildmeijer, Nilsson, Årestedt, & Perk, 2012). In our study twelve nurses from seven hospitals reviewed the medical records, which may be a potential weakness. However, it has been reported that identification of triggers and adverse events do not differ remarkably between different nurses in contrary to the judgments of preventability made by different teams comprising nurses and physicians (Unbeck et al., 2008). Another inborn potential weakness of reviewing medical records is the dependence upon the quality of the notes. Strength was that one senior colorectal surgeon being experienced and educated in patient safety work participated in all the judgments regarding adverse events together with the nurse who had reviewed a certain record, and sometimes together with other surgeons.

The rate of adverse events in general surgery has been reported to vary between 22% and 66% (Briant, Morton, Lay-Yee, Davis, & Ali, 2005; Gawande, Thomas, Zinner, & Brennan, 1999; Kable, Gibberd, & Spiegelman, 2002). In a systematic review of in-hospital adverse events operation-related events constituted 39.6%. Within general surgery adverse events occurred in 14–40% and about 40% of all adverse events were operation-related (de Vries, Ramrattan, Smorenburg, Gouma, & Boermeester, 2008). A national study comprising all 63 hospitals in Sweden with emergency service reported recently that an adverse event occurred in 15.4% among 3,301 patients within general surgery. The smallest hospitals had a significantly lower rate of adverse events. Due to the case mix it is unreliable to compare the different departments of surgery in our study because of the varying number of complicated patients, and the varying number of urgent admittances. Smaller hospitals had the lowest rate of adverse events, which may be due to less number of urgent admittances or of less stage IV patients. However, as mentioned above it cannot be excluded that detection and judgment of the triggers may have differed to some extent between the nurses reviewing the medical records (Schildmeijer et al., 2012). Wound infection and wound dehiscence were the commonest adverse events occurring altogether in 14% of the patients. This is higher than reported in the Surpass study comprising patients in general surgery where the rate of wound infection was four percent (de Vries et al., 2010). Furthermore some wound infections may have been overlooked in our study if they appeared after discharge from hospital. Hospital acquired infections were similar to the national study (36%). Prolonged hospital stay or readmission (category F according to NCC MERP) occurred in 19%, which is lower than in the National study comprising patients in general surgery (51.7%). In that study there was, however, no strict definition of prolonged stay. In the National study 5.8% of the patients had adverse events that caused a permanent injury or contributed to death, which was similar to the present study. In the end of 2012 some 38 patients had died. Stage IV disease was diagnosed initially in 42% and had as expected great impact on the outcome (Heedman et al., 2015). In addition 32% had localized disease showing that other causes of death are common, which has recently been reported (Sjödahl, Rosell, & Starkhammar, 2013).

No obvious differences in the pattern of adverse events were noted between the hospitals but fluid overload and gastric retention, which occurred in 8%, were less common in departments using the concept of ERAS (enhanced recovery after surgery) (Kehlet, 1997; Ljungqvist & Rasmussen, 2014). Anastomotic leakage was diagnosed in only two percent and most frequent after urgent admittance. This low figure may be due to readiness of making a stoma instead of an anastomosis in high-risk patients but there are no data supporting this assumption.

Hospital acquired pneumonia was diagnosed in 4% which is in accordance with other reports on all kinds of patients in a hospital level (SKL, 2014; Tablan et al., 2003). In the National Swedish study of general surgery including both operated and non-operated patients it was 1%. Unplanned intensive care (H) and permanent disability (G) were not documented but may in some cases be hidden in the patient group who died postoperatively.

The World Health Organization (WHO) has introduced a Safer Surgery Checklist, which has been reported to be associated with a reduction in major complications in eight hospitals around the world (Haynes et al., 2009). The WHO checklist was used by all hospitals in our study. However, it is well known that adverse events in patients who have undergone surgery often occur outside the operating room. Other checklists have been used to meet this and been associated with substantial reductions in surgical complications and postoperative mortality (de Vries et al., 2010).

Some areas for improvement have been identified. Measurement of body weight daily to avoid and/or to treat fluid overload is a rather simple way to decrease the risk for gastric retention, circulatory or respiratory insufficiency in some risk patients and to avoid impaired healing capacity of abdominal incisions or anastomoses. To reduce the rate of hospital acquired pneumonia a systematic work is under progress to prevent aspiration, reduce immobilization, and to improve oral care particularly in high-risk patients with severely disturbed physiology. Implementation should be done of various measures against surgical site infections (Song & Glenny, 1998), to keep normothermia perioperatively (Kurz, Sessler, & Lenhardt, 1996), to give supplemental oxygen (Greif, Akça, Horn, Kurz, & Sessler, 2000), and to keep glucose control in diabetics (Furnary & Wu, 2006). To implement various clinical measures for avoiding adverse events, checklists may be of value. Another measure of improvement is the use of ERAS, which has been shown to reduce the number of postoperative complications and length of stay in hospital (Kehlet, 1997). It is now used in elective colorectal surgery by all departments of surgery in the southeast region. In addition laparoscopic colonic surgery have been increasingly applied in elective surgery, which may reduce the number of adverse events of the abdominal wall in the future.

Recently the NHS England Never Events Taskforce summarized that to achieve a continual reduction in harm unwarranted variations must be reduced, learning from mistakes must be improved, and professional responsibility must continue to be promoted (The NHS Constitution England Never Events Taskforce, 2014). In addition to this, surgical safety research should focus on improving decision-making and performance in routine operations for complex patients and circumstances (Regenbogen et al., 2007).

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#### Competing Interests

The authors declare no competing interest.

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