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Impacts of the surgical safety checklist on postoperative clinical outcomes in gastrointestinal tumor patients

A single-center cohort study

Hao Wang, MD[a,b], Taohua Zheng, MB[c], Dong Chen, MD[b], Zhaojian Niu, MD[b], Xiaobin Zhou, PhD[d], Shikuan Li, MD[b], Yanbing Zhou, MD, PhD[b,*], Shougen Cao, MD[b,*]

Abstract

A 19-item surgical safety checklist (SSC) was published by the World Health Organization in 2008 and was proved to reduce postoperative complications. To date, however, the impacts of SSC implementation in China have not been evaluated clearly. The study was performed to evaluate the impacts of the SSC on postoperative clinical outcomes in gastrointestinal tumor patients.

Between April 2007 and March 2013, 7209 patients with gastrointestinal tumor who underwent elective surgery at the Affiliated Hospital of Qingdao University were studied. Data on the clinical records and outcomes of 3238 consecutive surgeries prior to SSC implementation were retrospectively collected; data on another 3971 consecutive surgeries performed after SSC implementation were prospectively collected. The clinical outcomes (including mortality, morbidity, readmission, reoperation, unplanned intervention and postoperative hospital stay) within postoperative 30 days were compared between the two groups. Univariate and multivariate logistic regression analysis were performed to identify independent factors for postoperative complications.

The rates of morbidity and in-hospital mortality before and after SSC implementation were 16.43% vs 14.33% ($P = .018$), 0.46% vs 0.18% ($P = .028$), respectively. Median of postoperative hospital stay in post-implementation group was shorter than that in pre-implementation group (8 vs 9 days, $P < .001$). Multivariable analysis demonstrated that the SSC was an independent factor influencing postoperative complications (odds ratio = 0.860; 95% CI, 0.750–0.988).

Implementation of the SSC could improve the clinical outcomes in gastrointestinal tumor patients undergoing elective surgery in China.

Abbreviations: ACCI = age-adjusted Charlson comorbidity index, DVT = manifesting as deep vein thrombosis, IQR = interquartile range, PE = pulmonary embolism, SSC = surgical safety checklist, VTE = venous thromboembolism, WHO = World Health Organization.

Keywords: gastrointestinal neoplasms, general surgery, surgical safety checklist

1. Introduction

Gastrointestinal tumors are some of the most common malignancies worldwide; in fact, gastric cancer and colorectal cancer represent the sixth and fourth most frequently detected malignancies among new cancer cases.[1,2] Despite advances in medical treatment, radical resection combined with regional lymphadenectomy is considered the only potential curative method for gastrointestinal tumors. Perioperative mortality from gastrointestinal tumors has decreased with the development of medical technology, surgical techniques and perioperative care; however, significant morbidity associated with the treatment for

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[a] Department of General Surgery, Dongying People's Hospital, Shandong, China, [b] Department of Gastrointestinal Surgery, [c] Hepatic Disease Center, Affiliated Hospital of Qingdao University, [d] Department of Epidemiology and Health Statistics, Qingdao University Medical College, Shandong, China.

[*] Correspondence: Yanbing Zhou, Department of Gastrointestinal Surgery, Affiliated Hospital of Qingdao University, No. 16, Jiangsu Rd, Qingdao City, Shan Dong Province, China (e-mail: yanbingzhou999@hotmail.com); Shougen Cao, Department of Gastrointestinal Surgery, Affiliated Hospital of Qingdao University, No. 16, Jiangsu Rd, Qingdao City, Shan Dong Province, China (e-mail: briancao@126.com).

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gastric and colorectal cancer is still observed. Postoperative complication rates ranging from 10.5% to 40.1%[3–7] and from 18% to 38%[8–13] have been respectively determined among gastric and colorectal cancer patients. Postoperative complications may mean death, unplanned reoperation, readmission, and prolonged length of hospital stay,[14–16] which are devastating to patients and costly to the health care system.[17] In fact, the rates of postoperative mortality and unplanned reoperation ranged from 0 to 3.0%[4–7] and from 1.7% to 1.9%[6] among gastric cancer patients; from 0.5% to 3.9%[9,10,12,13], and from 2% to 5%[8,10–13] among colorectal cancer patients, respectively. Moreover, the 30-day readmission rate has been reported from 9% to 12%[10,12,13] after general surgeries. Thus, reducing the occurrence of adverse events following gastrointestinal surgery has been studied by many researchers.

It has been reported that approximately half of all adverse events resulting in death or disability are attributable to errors and therefore preventable.[18,19] Several studies have shown that postoperative mortality and morbidity can be reduced significantly with efficient team communication and teamwork.[20–22] In 2008, the Safe Surgery Save Lives study group at the World Health Organization (WHO) published the results of implementing a perioperative SSC. A study has shown that the safety of surgery increases in developing and developed countries with WHO SSC implementation.[23] Based on these results, the WHO developed a 19-item SSC system. Since its conception, an increasing number of countries, hospitals, and health care facilities have implemented or are planning to implement this guideline.[24–27]

In 2010, the SSC system was promulgated by the National Health and Family Planning Commission of the People's Republic of China.[28] All hospitals in China were required to implement this system. Our previous investigation showed that the implementation of the SSC was feasible and effective for avoidance of risks in selective operations, and conducive to promoting communication among the surgical team and preventing surgical errors. Since the last four years, however, the effects of SSC implementation in China have not been evaluated. Moreover, until now, there was no research concentrating on gastrointestinal tumors in the world. This study aimed to evaluate the impact of the checklist on postoperative clinical outcomes following implementation in gastrointestinal tumor patients.

2. Methods

2.1. Study design

Data were obtained from the Gastrointestinal Tumor Database of the Affiliated Hospital of Qingdao University. The research proposal was approved by the ethics committee of the hospital. The study included all consecutively enrolled patients (16 years of age or older) with gastrointestinal tumors who underwent elective surgical procedures at the Affiliated Hospital of Qingdao University between April 2007 and March 2013. Operations were performed by doctors who had either over 5 years of experience or performed 500 operations. Patients were divided into two groups on April 1, 2010, on which day the SSC was implemented. Data was retrospectively studied as the baseline in the pre-implementation group. The SSC was strictly monitored in the post-implementation group and data obtained were prospectively studied.

2.2. Intervention

The SSC was formally introduced on March 26, 2010. All of the doctors, anesthetists, and nurses participating in this program were trained adequately according to surgical safety checklist (SSC) published by WHO,[24] as described in Table 1. Intervention included three phases: sign-in, time out, and sign-out. Prior to sign-in, the patient was identified by the nurses and doctors twice in the ward and outside of the operation room.

The "sign-in" procedure was performed by the surgeon before anesthesia in accordance with the SSC. "Time out" was performed by the circulating nurse at the beginning of incision. At this time, all operating staff ceased from performing other tasks except completing the checklist. Upon completion of the operation, the circulating nurse accomplished the "sign-out" checklist. In this program, surgeons, anesthetists, circulating nurses, and scrubbing nurses were required to implement the checklist from the beginning to the end of the operation and signed their names on the sheets required afterward.

2.3. Data collection

Data were obtained from the Gastrointestinal Tumor Database of the Affiliated Hospital of Qingdao University. All data collectors received training and supervision from the primary investigators regarding the identification and classification of complications and process measures and had more than 5 years collecting experience. They followed up the patients until discharge or for 30 days. Clinical outcomes were identified through chart monitoring and communication with clinical staff. All patient data were entered into the electronic database.

Data included the demographic characteristics of patients, characteristics of tumors, procedural data, type of anesthetic administered, length of hospital stay, readmission, reoperation, unplanned intervention, mortality and postoperative complications. Postoperative complications, particularly major complications and death, were recorded. This variable included any occurrence of 20 complications recorded in the American College of Surgeons' National Surgical Quality Improvement Program[34]; complications included surgical site infection (superficial, deep, or organ-space), wound disruption, pneumonia, unplanned intubation, pulmonary embolism, on ventilator for over 48 hours, progressive renal insufficiency or acute renal failure requiring dialysis, urinary tract infection, stroke, coma, cardiac arrest requiring cardiopulmonary resuscitation, myocardial infarction, bleeding requiring transfusion, deep venous thrombosis requiring therapy, sepsis or septic shock, unplanned return to the operating room, and death. Postoperative complications were also categorized according to the Clavien-Dindo classification.[35]

2.4. Statistical analysis

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 18.0, Chicago, IL) and Microsoft Office Excel 2007. Differences between the pre- and post-implementation groups were assessed by chi-square test, independent-samples t test and Wilcoxon rank sum tests (nonparametric test, Mann–Whitney U test), as appropriate. Data were correspondingly reported as numbers (percentage), means (standard deviation), or medians with inter-quartile range (IQR).

Table 1

The World Health Organization surgical safety checklist[24].

Before induction of anesthesia (with at least nurse and anesthetist)	Before skin incision (with nurse, anesthetist and surgeon)	Before patient leaves operating room (with nurse, anesthetist and surgeon)
Has the patient confirmed his/her identity, site, procedure, and consent? • Yes	• Confirm all team members have introduced themselves by name and role.	Nurse verbally confirms: •The name of the procedure •Completion of instrument, sponge, and needle counts •Specimen labeling (read specimen labels aloud including patient name) • Whether there are any equipment problems to be addressed
	• Confirm the patients name, procedure, and where the incision will be made.	
Is the site marked? • Yes • Not applicable		
	Has antibiotic prophylaxis been given within the last 60 min? • Yes • Not applicable	
Is the anesthesia machine and medication check complete? • Yes		
	Anticipated critical events to surgeon: • What are the critical or nonroutine steps? • How long will the case take? • What is the anticipated blood loss?	
Is the anesthesia machine and medication check complete? • Yes		
		To surgeon, anesthetist, and nurse: • What are the key concerns for recovery and management of this patient?
Is the pulse oximeter on the patient and functioning? • Yes		
	Anticipated critical events to surgeon: • What are the critical or nonroutine steps? • How long will the case take? • What is the anticipated blood loss? To anesthetist: • Are there any patient-specific concerns? To nursing team: • Has sterility (including indicator results) been confirmed? • Are there equipment issues or any concerns? Is essential imaging displayed? • Yes • Not applicable	
Is the pulse oximeter on the patient and functioning? • Yes Does the patient have a: Known allergy? • No • Yes Difficult airway or aspiration risk? • No •Yes, and equipment/assistance available Risk of >500 ml blood loss (7 mg/kg in children) • No • Yes, and two IVs/central access and fluids planned		

Table 2

Baseline characteristics of the cohort (*N* = 7209).

	Pre-implementation *N* = 3238	Post-implementation *N* = 3971	P
Male gender	2104 (64.97)	2609 (65.70)	.386
Age, y, mean (IQR)	60 (52,70)	61 (54,70)	.001
Comorbidities	1498 (46.26)	2079 (52.35)	<.001
Hypertension	404	537	
Coronary artery disease	387	516	
Diabetes mellitus	317	418	
Renal insufficiency	135	191	
Liver insufficiency	126	188	
Pulmonary disease	92	121	
Neurologic disease	83	123	
Age-adjusted Charlson comorbidity index (ACCI) Median (IQR)	2 (1–3)	2 (1–3)	.673
Surgical procedure (n, %)			.069
Partial gastrectomy	1183 (36.53)	1317 (33.17)	
Total gastrectomy	434 (13.40)	504 (12.69)	
Right hemicolectomy	319 (9.85)	434 (10.93)	
Left hemicolectomy	334 (10.32)	458 (11.53)	
Dixon operation	576 (17.79)	753 (18.96)	
Hartmann operation	127 (3.92)	156 (3.93)	
Miles operation	234 (7.23)	311 (7.83)	
Small bowel resection	31 (0.96)	38 (0.96)	
T-N-M Stage			.139
Stage I	596 (18.41)	692 (17.43)	
Stage II	1058 (32.67)	1309 (32.96)	
Stage III	1049 (32.40)	1376 (34.65)	
Stage IV	438 (13.53)	477 (12.01)	
Not specified	97 (2.30)	117 (2.95)	
Invasion of neighbor	472 (14.58)	565 (14.23)	.675
ASA classification			.057
I	168 (5.19)	247 (6.22)	
II + III	3016 (93.14)	3675 (92.55)	
IV	54 (1.67)	49 (1.23)	
General anesthesia	1889 (58.34)	3174 (79.93)	<.001
Combined resection	175 (5.40)	289 (7.28)	.001
Operative duration (mins) median (IQR)	150 (110–190)	145 (110–180)	.351
Blood loss (ml) median (IQR)	220 (90–350)	215 (80–350)	.127

Additionally, univariate and multivariate logistic regression analysis were performed to find out the relationship between SSC and postoperative complications after removing the confounding factors. The presence or absence of postoperative complications was used as a dependent variable. Variables, including preoperative conditions, tumor-related factors, surgical procedures, and SSC implementation, were designated as independent variables. Unordered categorical variables were analyzed by applying dummy variables, and odds ratios and 95% CIs were calculated for each parameter in both groups. A P value $<.05$ was considered statistically significant.

3. Results

3.1. Clinicopathologic and treatment characteristics

The pre-implementation cohort consisted of 3238 patients and 3971 patients were enrolled in the post-implementation cohort. Characteristics of the patients are listed in Table 2. There were no significant differences in gender, age-adjusted Charlson comorbidity index (ACCI), surgical procedures, TNM stage, invasion of neighbors, ASA classification, operative duration, and blood loss. However, some differences between the pre-implementation and post-implementation cohort were observed. There were more patients with comorbidities in the post-implementation cohort. Patients in the post-implementation cohort were more likely to undergo general anesthesia and combined resection procedures.

3.2. Clinical outcomes

A total of 1098 patients experienced postoperative complications within 30 days, for an overall morbidity rate of 15.23%. Figure 1 showed that in the first 3 years before SSC implementation, the morbidity rates were 16.14% (154/954), 16.18% (167/1032), and 16.61% (208/1252), respectively, which were higher than the overall rate; while the morbidity rates in the 3 years afterward were 14.29% (179/1253), 14.15% (191/1350), and 14.55% (199/1368), which were lower than the overall one. The morbidity rates were relatively stable in the 3-year period before implementation and afterward. Rates of complications in all sites decreased from 16.34% (529/3238) at baseline to 14.33% (569/3971) after introduction of the checklist ($P = .018$); total in-hospital mortality also decreased from 0.48% (15/3238) to 0.18% (7/3971) ($P = .028$; Table 3). The overall rate of surgical site infection decreased significantly in the post-implementation group ($P = .003$). There was no difference between two groups on unplanned reoperation or 30-day readmission. Median of postoperative hospital stays prior to checklist implementation

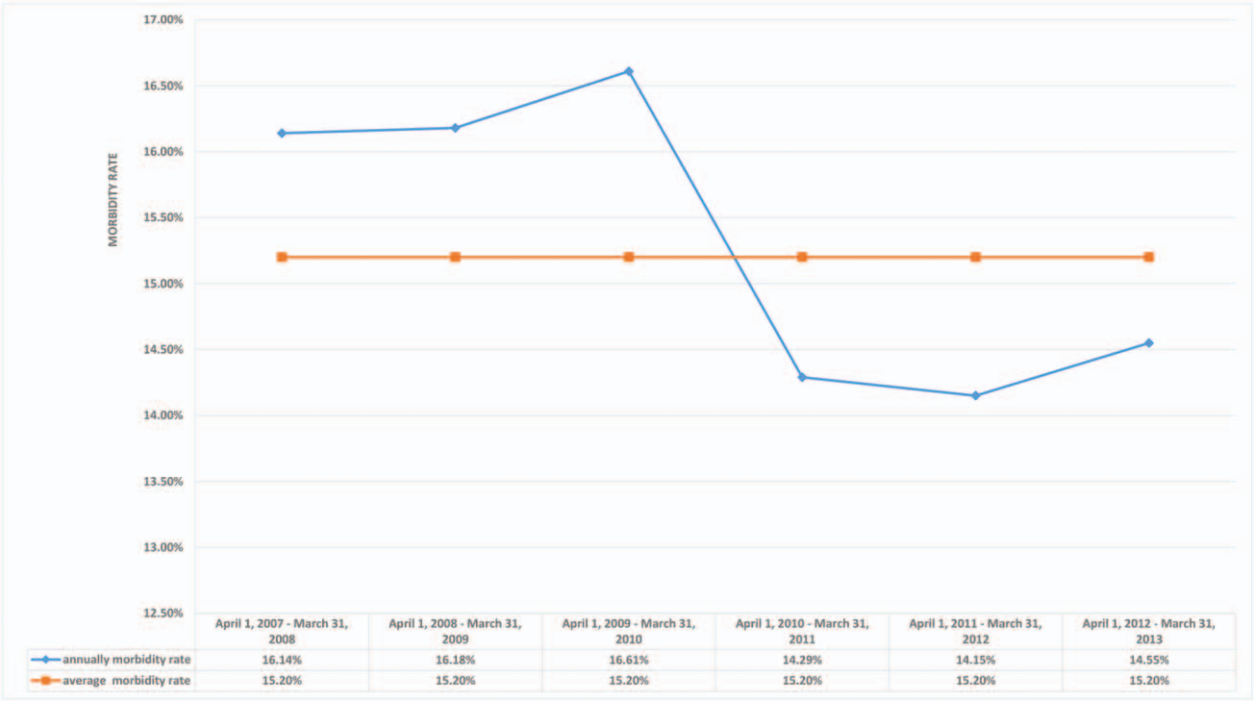

Figure 1. Annual postoperative morbidity rate of the cohort ($N = 7209$).

was 9 days, which was 1 day longer than those observed afterward ($P < .001$).

3.3. Relationship between the SSC and postoperative complications

Univariate logistic analysis showed that the variable selection process yielded 11 variables, including SSC, that were closely related to the occurrence of complications after surgery. Of the 11 variables, age, TNM stage, ASA score, combined resection, invasion of neighboring organs, comorbidity, surgical procedure, volume of intraoperative blood loss, operating time, and anesthesia were risk factors whereas the SSC was a protective factor. Statistical data are outlined in Table 4.

Multivariate logistic analysis showed (Table 5) that variables, including SSC, age, TNM stage II, ASA score IV, combined resection, invasion of neighboring organs, comorbidities, surgical procedures of Dixon and Miles operations, volume of intraoperative blood loss, operation time, and epidural anesthesia were independent risk factors for postoperative complications. After adjustment, the SSC remained significantly related to postoperative complications with an OR of 0.853 (95% CI = 0.743–0.979).

Table 3

The clinical outcomes of the cohort ($N = 7209$).

	Pre-implementation $N = 3238$	Post-implementation $N = 3971$	*P* Value
Any complications	529 (16.34)	569 (14.33)	.018
Hemorrhage	25 (0.77)	42 (1.06)	.209
Leakage	69 (2.13)	66 (1.66)	.144
Surgical-site infection	274 (8.46)	263 (6.62)	.003
Wound disruption	34 (1.05)	29 (0.73)	.147
Cardiovascular complications	22 (0.68)	15 (0.38)	.075
Pulmonary complications	62 (1.91)	72 (1.81)	.751
Deep-vein thrombosis	10 (0.31)	3 (0.08)	.020
Unplanned reoperation	76 (2.35)	80 (2.01)	.334
Unplanned intervention	26 (0.80)	26 (0.65)	.459
Readmissions	77 (2.38)	81 (2.01)	.329
Death	15 (0.46)	7 (0.18)	.028
Hospital stay, d, median (IQR)	14 (12, 17)	13 (11.16)	< .001
Postoperative hospital stay, d, median (IQR)	9 (7, 11)	8 (7, 10)	< .001

3.4. Severity of postoperative complications

Nonparametric tests showed a significant difference between the two groups in terms of grade of postoperative complications according to the Clavien-Dindo surgical classification system ($Z = -2.486$, $P = .013$). Table 6 shows that there was no difference in the proportion of Grade I, Grade IIIa, Grade IIIb, and Grade IVa complications between two groups. While the proportion of Grade II, Grade IVb, and Grade V complications before checklist was significantly higher than that afterward. The complications before checklist implementation were more serious than those afterward.

4. Discussion

Surgery is one of the most complex health interventions for patients with gastrointestinal tumor. It can prevent loss of life or limb but cause adverse events that vary between individual patients.[18] On the one hand, surgical resection combined regional lymphadenectomy has always been considered as the only potentially curative method for gastrointestinal tumors; on

Table 4

Univariate logistic analysis of risk factors related to postoperative morbidity in 7209 patients.

Patient variable	No. postoperative complications ($N=6111$)		Postoperative complications ($N=1098$)		P	Odd ratio	95%CI
Age, y, median (IQR)	61 (53,69)		62 (54,72)		.014	1.014	1.008–1.019
Operative time, h, median (IQR)	2.33 (1.92,2.92)		2.67 (2.17,3.33)		0.001	1.535	1.429–1.649
Intraoperative blood loss, 100 ml, median (IQR)	3 (2,4)		3 (2,4)		<0.001	1.087	1.059–1.115
	n	%	*n*	%			
Checklist implementation					0.018		
Before	2709	83.7	529	16.3		1	
After	3402	85.7	569	14.3		0.857	0.753–0.974
Gender					0.313		
Male	3989	84.5	734	15.5%		1	
Female	2122	85.4	364	14.6		0.932	0.813–1.068
Comorbidities					<0.001		
No	3184	87.7	448	12.3		1	
Yes	2927	81.8	650	18.2		1.578	1.385–1.798
Surgical procedure					0.043		
Partial gastrectomy	2151	86.0	349	14		1	
Total gastrectomy	799	85.2	139	14.8	0.521	1.072	0.867–1.326
Right hemicolectomy	641	85.1	112	14.9	0.529	1.077	0.855–1.356
Left hemicolectomy	680	85.9	112	14.1	0.898	1.015	0.808–1.277
Dixon operation	1104	83.1	225	16.9	0.014	1.256	1.046–1.508
Hartmann operation	239	84.5	44	15.5	0.468	1.135	0.807–1.595
Miles operation	439	80.6	106	19.4	0.001	1.488	1.170–1.893
Small bowel resection	58	84.1	11	15.9	0.640	1.169	0.608–2.249
TNM Stage					0.004		
Stage I	1122	87.1	166	12.9		1	
Stage II	1980	83.7	387	16.3	0.005	1.321	1.086–1.607
Stage III	2029	83.7	396	16.3	0.005	1.319	1.085–1.604
Stage IV	788	86.1	127	13.9	0.500	1.089	0.850–1.396
Not specified	192	89.7	22	10.3	0.287	0.774	0.484–1.240
Invasion of neighbor					0.004		
No	5263	85.3	909	14.7		1	
Yes	848	81.8	189	18.2		1.290	1.086–1.534
ASA score					0.001		
I	367	88.4	48	11.6		1	
II + III	5669	92.8	1022	7.2	0.041	1.378	1.013–1.876
IV	75	72.8	28	27.2	<0.001	2.854	1.683–4.840
Anesthesia					<0.001		
General anesthesia	4351	85.9	712	14.1		1	
Epidural anesthesia	1760	82.0	386	18.0		1.340	1.170–1.535
Combined resection					0.005		
No	5738	85.1	1006	14.9		1	
Yes	373	80.2	92	19.8		1.407	1.109–1.784

the other hand, postoperative complications occasionally happen because the patients with gastrointestinal tumor are usually associated with risk factors such as old age, malnutrition, decreased organ reserve, neoadjuvant therapy, or concomitant comorbidities (hypertension, diabetes mellitus, ischemic heart disease, brain infarction, chronic lung disease, or chronic renal insufficiency) for morbidity. Moreover, intra-abdominal general surgery procedures, including resection and reconstruction, are much more likely to be associated with morbidity than those outside the abdomen all together.[36]

With the aim of reducing adverse events, a 19-item checklist was developed by the WHO Patient Safety Program. Previous studies suggest that implementation of this checklist can improve clinical outcomes. Haynes et al[23] conducted a study on the effectiveness of the WHO SSC in eight hospitals worldwide and found that morbidity and mortality rates decreased from 11% to 7.0% and 1.5% to 0.8%, respectively. de Vries et al[14] also evaluated the use of the WHO SSC prior and subsequent to implementation in a controlled multicenter prospective study; in their work, implementation of the checklist was associated with decreased surgical complications and mortality. Other studies on the effects of checklist implementation have been performed and similar results have been obtained.[37–41] However, a Canadian study found that implementation of the SSC in Ontario did not correlate with significant reductions in operative mortality or complications.[42] A systematic analysis[43] showed that implementation of the WHO SSC results in decreased postoperative complications, mortality, and surgical site infection.

The present study revealed that implementation of the SSC in our hospital was associated with decreases in in-hospital 30-day morbidity from 16.34% to 14.33% as well as decreases in overall in-hospital mortality from 0.46% to 0.18%. The surgical site

Table 5

Multivariate logistic analysis of the postoperative morbidity.

Variable	Beta	P	Adjusted odds ratio for postoperative complications	95%CI
Age, y	0.010	.001	1.010	1.004–1.016
Operation time (h)	0.452	<.001	1.571	1.452–1.700
Intraoperative blood loss (per 100 mL)	0.023	.041	1.024	1.001–1.048
Checklist implementation	-0.159	.024	0.853	0.743–0.979
Comorbidities	0.368	<.001	1.471	1.277–1.694
surgical procedures		.002		
Partial gastrectomy			1	
Total gastrectomy	−0.059	0.597	0.943	0.758–1.173
Right hemicolectomy	0.146	0.278	1.157	0.889–1.507
Left hemicolectomy	0.118	0.322	1.125	0.891–1.703
Dixon operation	0.305	0.002	1.357	1.123–1.639
Hartmann operation	0.190	0.276	1.210	0.859–1.703
Miles operation	0.423	0.001	1.527	1.194–1.952
Small bowel resection	0.519	0.189	1.681	0.774–3.650
TNM Stage		0.041		
Stage I			1	
Stage II	0.223	0.031	1.250	1.021–1.531
Stage III	0.191	0.065	1.210	0.989–1.481
Stage IV	0.006	0.965	1.006	0.763–1.325
Not specified	–0.288	0.307	0.750	0.432–1.303
Invasion of neighbor	0.203	0.044	1.225	1.006–1.491
ASA score		0.035		
I			1	
II + III	0.104	0.524	1.110	0.805–1.531
IV	0.620	0.029	1.859	1.065–3.244
Epidural anesthesia	0.242	0.001	1.273	1.099–1.475

infection was responsible for the main reduction of postoperative complications and the complications in pre-implementation group were more serious, in spite of the patients in the post-implementation group were older and have more comorbidity than pre-implementation one.

Improvements in outcomes after checklist implementation could be attributed to several mechanisms. First, all of the operating room staff was required to participate in the SSC program. Surgeons, anesthetists, and nurses were required to communicate with each other regarding the patient's condition, surgical procedure, estimated operative time, and intraoperative blood loss, among others. Several studies show that efficient team communication and teamwork could improve patient safety and quality, as well as prevent death and major complications during surgery,[20–22,44,45] with rates of complications and deaths reduced by as much as 80%.[22] Effective communication can also lead to reductions in time in the operating room, which is correlated with reductions in adverse events.[37] In our study, with the SSC implementation, the rates of postoperative complications and mortality decreased as much as 12.3% and 60.9%, respectively, and the median of postoperative hospital stays prior to checklist implementation was 1 day longer than those observed afterward, venous thromboembolism (VTE), manifesting as deep vein thrombosis (DVT), or pulmonary embolism (PE), represents clinically significant complication among the patients undergoing surgery for gastrointestinal malignancy. The incidence of DVT ranges from 2.1% to 5% in this population.[46,47] In the present study, the incidence of DVT was 0.31% in the pre-implementation group, and 0.08% in the post-implementation group ($P = .02$). This incidence was lower than the rates reported in the previous studies. The difference may be associated with our emphasis of VTE prophylaxis during perioperative period. And also, there were no essential differences in terms of prophylaxis for VTE in the different periods. Intensive prophylaxis for VTE was routinely given to all the patients either in post- or pre-implementation group to minimize the risk of sudden death from fatal PE. The prophylaxis for VTE included dynamic assessment, patient education, mechanical prophylaxis (graduated compression stockings and intermittent pneumatic compression devices), early ambulation, and pharmacologic prophylaxis (if no contraindication). In our study, the implementation of surgical safety checklist decreased the incidence of DVT. The mechanisms of benefits from checklist implementation remains unclear. However, specific items on the checklist may directly prevent adverse events. For example, checking the timely intraoperative usage of intermittent pneumatic compression device and graduated compression stockings could prevent the DVT. Finally, item by item, the checklist implementation may result in decreased morbidity and mortality by improving teamwork, communication, and attitudes toward quality and safety.

Table 6

Clinical Outcomes of 7209 patients Classified according to the Clavien–Dindo System.

Grade of complications	Pre-implementation N = 3238	Post-implementation N = 3971	P Value*
None	2709 (83.67)	3402 (85.67)	.018
Grade I	196 (6.05)	243 (6.12)	.907
Grade II	119 (3.68)	102 (2.57)	.007
Grade IIIa	108 (3.34)	119 (3.00)	.413
Grade IIIb	60 (1.85)	68 (1.71)	.653
Grade IVa	15 (0.46)	23 (0.58)	.499
Grade IVb	16 (0.49)	7 (0.18)	.017
Grade V	15 (0.46)	7 (0.18)	0.028

* Compared by the proportion.

Mann–Whitney U test: $Z = -2.486$, $P = .013$.

The WHO SSC emphasizes the application of potentially lifesaving measures, such as anesthesia instrument check, pulse oximetry, preparing for intravenous, etc. These measures can improve patient safety in the operating room.[48] Antibiotics must be administered 30 minutes before incision in the operating room rather than in the ward, where delays are frequent. Using the checklist, the rate of surgical site infection is significantly decreased and complications become less serious.[41] Our study showed that with the SSC, the rate of surgical site infection was reduced from 8.46% to 6.62%. Finally, Hawthorne effect could be another possible reason. Data of the post-implementation group were prospectively collected. In this group, the surgical teams maybe pay more attention on the patients, which results in reducing the postoperative complications.

This study presents several limitations. First, the WHO SSC was introduced in March 26, 2010 and all hospitals in China were required to implement this system; however, a randomized study design was not presented. Second, the study was conducted for six years to obtain sufficient numbers of cases; thus, some of the variables may have changed and surgeon experience may have improved. Patients with gastrointestinal tumors who underwent surgery in a single institute were enrolled to prevent

differences in diseases, hospitals, and doctors. Operating doctors were required to have over five years of experience or performed 500 operations to ensure that their surgical skills are relatively stable. In this study, the morbidity rates were relatively stable in the 3-year period before checklist and afterward, respectively. To decrease confounding factors, multivariate logistic regression analysis was used to obtain independent risk factors. In the model of postoperative complications, the WHO SSC emerged as a significant predictor of patient outcome, even after controlling for age, gender, comorbidity, surgical procedures, TNM stage, ASA score, anesthesia, combined resection, operative time, and intraoperative blood loss. Findings showed that postoperative complications in patients intervened under the WHO SSC decreased by about 14%.

Compliance with the WHO SSC further limited this study. The effectiveness of the WHO SSC depends on checklist compliance.[49] However, we and other researchers found that compliance with the guidelines of the SSC varies worldwide.[29–33] Pickering et al[32] found that meaningful compliance with the WHO SSC is lower than that indicated by administrative data, particularly in the sign-out section. A previous investigation from us showed that the compliance of SSC was different in different operating team.[33] In the present study, all operating staff members participated in three 60-minute training sessions, including formatting a multidisciplinary team, making a "how-to" video, and small simulation testing, to ensure correct and proper completion of the checklist. The supervisor in charge checked the compliance of the checklist regularly and occasionally. Regular and extra meetings with the entire operating room staff were conducted, during which records were reviewed and the importance of the checklist was emphasized. All of the SSC in this study were completed appropriately.

In conclusion, the WHO SSC decreases postoperative complication rates, particularly surgical-site infection, mortality rates and hospital stay. The WHO SSC is a simple and inexpensive method that helps improve postoperative clinical outcomes for patients with gastrointestinal tumors. As this research is a single-center study concentrating on gastrointestinal tumors, multicenter studies should be undertaken in future work.

Author contributions

Data curation: Dong Chen, Xiaobin Zhou.
Formal analysis: Xiaobin Zhou.
Funding acquisition: Yanbing Zhou.
Investigation: Hao Wang, Taohua Zheng.
Methodology: Dong Chen.
Resources: Shikuan Li, Yanbing Zhou.
Software: Taohua Zheng.
Supervision: Shougen Cao, Yanbing Zhou.
Validation: Zhaojian Niu.
Visualization: Zhaojian Niu.
Writing – original draft: Hao Wang.
Writing – review & editing: Shougen Cao.

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