Impacts of the Surgical Safety Checklist on Postoperative Clinical Outcomes in Gastrointestinal Tumor Patients: A Single-center Cohort Study

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Abstract

Background: 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.

Study Design: Between April 2007 and March 2013, 7,209 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 3,238 consecutive surgeries prior to SSC implementation were retrospectively collected; data on another 3,971 consecutive surgeries performed after implementation of the checklist system was 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.

Results: The rates of morbidity and in-hospital mortality prior to and after checklist implementation were 16.43% vs. 14.33% (P=0.018), 0.46% vs. 0.18% (P=0.028), respectively. Median of postoperative hospital stay before checklist implementation was 1 day longer than that observed afterward (P<0.001). Multivariable analysis demonstrated that the SSC was an independent factor influencing any postoperative complications (odds ratio =0.860; 95% CI, 0.750 to 0.988).

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

Keywords: Gastrointestinal neoplasms; General surgery; Surgical safety checklist

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 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] has 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 surgery operations. 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 Saves 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 avoiding 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.

Methods

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.

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. 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.

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, and 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 [29]; complications included surgical site infection (superficial, deep, or organ-space), wound disruption, pneumonia, unplanned intubation, pulmonary embolism, on ventilator for over 48 hrs, 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 [30].

Statistical analysis

All statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 18.0, Chicago, IL, USA) 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 (non-parametric test, Mann–Whitney U test), as appropriate. Data were correspondingly reported as numbers (percentage), means (standard deviation), or medians with Inter-Quartile Range (IQR). Additionally, univariate and multivariate logistic regression
Committee on Cancer (AJCC) staging system, 1288 (17.87%), 2367 patients have more than one. According to the 7th edition American cases have one comorbidity and the remaining 1076 (30.08%) (n=735, 20.55%), pulmonary diseases (n=213, 5.95%); of these, 2501 (n=1844, 51.55%), malnutrition (n=846, 23.65%), diabetes mellitus have comorbidities before operation, including heart diseases cancer (n=7013, 97.3%), and the remaining were benign tumor or and rectum (n=2157, 29.92%). The majority of the tumor were (including duodenum, n=69, 0.96%), colon (n=1545, 21.43%) of the tumor was on stomach (n=3438, 47.69%), small intestine (including duodenum) 31 (0.96) 38 (0.96) 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) 0.675 ASA classification I 168 (5.19) 247 (6.22) II 2179 (67.29) 2755 (69.38) III 1058 (32.67) 1309 (32.96) IV 54 (1.67) 49 (1.23) General anesthesia 1889 (58.34) 2174 (54.34) Combined resection 175 (5.40) 289 (7.28) 0.001

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 = 0.018); total in-hospital mortality also decreased from 0.48% (15/3238) to 0.18% (7/3971) (P = 0.028; Table 2). The overall rate of surgical site infection decreased significantly in the post-implementation group (P = 0.003). There was no difference between two groups on unplanned reoperation or 30-day readmission. Median of postoperative hospital stay after checklist implementation was 9 days, which was 1 day shorter than those observed afterward (P < 0.001).
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, T-N-M stage, ASA score, combined resection, invasion of neighboring organs, comorbidity, and tumor location, 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 3.

Multivariate logistic analysis showed in Table 4 that variables, including SSC, age, T-N-M stage II, ASA score IV, combined resection, invasion of neighboring organs, comorbidities, tumor located on small intestine and rectal, volume of intra-operative blood loss, operating 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 0.860 (95% CI=0.750 to 0.988).

Table 3: Risk factors related to postoperative morbidity in 7209 patients.

<table>
<thead>
<tr>
<th>Patient variable</th>
<th>No postoperative complications (N=6111)</th>
<th>Postoperative complications (N=1098)</th>
<th>P Value</th>
<th>Odd ratio</th>
<th>95% CI</th>
</tr>
</thead>
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<tr>
<td>Age, y, median (IQR)</td>
<td>61 (53,69)</td>
<td>62 (54,72)</td>
<td>0.014</td>
<td>1.014</td>
<td>1.008-1.019</td>
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<td>Operative time, h, median (IQR)</td>
<td>2.33 (1.92,2.92)</td>
<td>2.67 (2.17,3.33)</td>
<td>&lt;0.001</td>
<td>1.535</td>
<td>1.429-1.649</td>
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<td>Intraoperative blood loss, 100ml, median (IQR)</td>
<td>3 (2,4)</td>
<td>3 (2,4)</td>
<td>&lt;0.001</td>
<td>1.087</td>
<td>1.059-1.115</td>
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<td>Checklist implementation</td>
<td></td>
<td></td>
<td>0.018</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before</td>
<td>2709</td>
<td>83.7</td>
<td>529</td>
<td>16.3</td>
<td>1</td>
</tr>
<tr>
<td>After</td>
<td>3402</td>
<td>85.7</td>
<td>569</td>
<td>14.3</td>
<td>0.857</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td>0.313</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3989</td>
<td>84.5</td>
<td>734</td>
<td>15.50%</td>
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<tr>
<td>Female</td>
<td>2122</td>
<td>85.4</td>
<td>364</td>
<td>14.6</td>
<td>0.932</td>
</tr>
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<td>Comorbidities</td>
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<td></td>
<td>&lt;0.001</td>
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<td>3184</td>
<td>87.7</td>
<td>448</td>
<td>12.3</td>
<td>1</td>
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<td>Yes</td>
<td>2927</td>
<td>81.8</td>
<td>650</td>
<td>18.2</td>
<td>1.578</td>
</tr>
<tr>
<td>Tumor location</td>
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<td></td>
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<td></td>
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<td>Stomach</td>
<td>2950</td>
<td>85.8</td>
<td>488</td>
<td>14.2</td>
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<td>Small intestine (including duodenum)</td>
<td>58</td>
<td>84.1</td>
<td>11</td>
<td>15.9</td>
<td>0.681</td>
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<tr>
<td>Colon</td>
<td>1332</td>
<td>86.2</td>
<td>213</td>
<td>13.8</td>
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<td>Rectal</td>
<td>1771</td>
<td>82.1</td>
<td>386</td>
<td>17.9</td>
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<td>1980</td>
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<td>387</td>
<td>16.3</td>
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<tr>
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<td>89.7</td>
<td>22</td>
<td>10.3</td>
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<tr>
<td>Invasion of neighbor</td>
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<td>0.004</td>
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<td>5283</td>
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<td>909</td>
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<tr>
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<td>81.8</td>
<td>189</td>
<td>18.2</td>
<td>1.29</td>
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<tr>
<td>ASA score</td>
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<tr>
<td>I</td>
<td>367</td>
<td>88.4</td>
<td>48</td>
<td>11.6</td>
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</tr>
<tr>
<td>II</td>
<td>4244</td>
<td>86</td>
<td>690</td>
<td>14</td>
<td>0.171</td>
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<tr>
<td>III</td>
<td>1425</td>
<td>81.1</td>
<td>332</td>
<td>18.9</td>
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<td>Combined resection</td>
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<td></td>
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<td>85.1</td>
<td>1006</td>
<td>14.9</td>
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<tr>
<td>Yes</td>
<td>373</td>
<td>80.2</td>
<td>92</td>
<td>19.8</td>
<td>1.407</td>
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</table>
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 ($Z = -2.486, P = 0.013$). Table 5 shows that there was no difference in the proportion of Grade I, Grade IIIa, Grade IIIb and Grade IVa complications between 2 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.

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 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 [31].

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 and colleagues [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 from 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 [32-36]. However, a Canadian study found that implementation of the SSC in Ontario did not correlate with
significant reductions in operative mortality or complications [37]. A systematic analysis [38] 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 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 intra-operative 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 [20-22,39,40] 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 [41,42]. 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.

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 46. Antibiotics must be administered 30 min 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 [36]. 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 may 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. Potential confounders maybe find by secular trend. 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, tumor location, 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 [42]. However, we and other researchers found that compliance with the guidelines of the SSC varies worldwide [43-47]. Pickering and colleagues 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 [47]. 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, multi-center studies should be undertaken in future work.

References
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