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Effect of a risk-stratified intervention strategy on surgical complications: experience from a multicentre prospective study in China

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ABSTRACT

Objectives To develop a risk-stratified intervention strategy and evaluate its effect on reducing surgical complications.

Design A multicentre prospective study with preintervention and postintervention stages: period I (January to June 2015) to develop the intervention strategy and period II (January to June 2016) to evaluate its effectiveness.

Setting Four academic/teaching hospitals representing major Chinese administrative and economic regions.

Participants All surgical (elective and emergent) inpatients aged ≥14 years with a minimum hospital stay of 24 hours, who underwent a surgical procedure requiring an anesthesiologist.

Interventions Targeted complications were grouped into three categories (common, specific, serious) according to their incidence pattern, severity and preventability. The corresponding expert consensus-generated interventions, which focused on both regulating medical practices and managing inherent patient-related risks, were implemented in a patient-tailored way via an electronic checklist system.

Primary and secondary outcomes Primary outcomes were (1) in-hospital death/confirmed death within 30 days after discharge and (2) complications during hospitalisation. Secondary outcome was length of stay (LOS).

Results We included 51 030 patients in this analysis (eligibility rate 87.7%): 23 413 during period I, 27 617 during period II. Patients' characteristics were comparable during the two periods. After adjustment, the mean number of overall complications per 100 patients decreased from 8.84 to 7.56 (relative change 14.5%; P<0.0001). Specifically, complication rates decreased from 3.96 to 3.65 (7.8%) for common complications (P=0.0677), from 0.50 to 0.36 (28.0%) for specific complications (P=0.0153) and from 3.64 to 2.88 (20.9%) for serious complications (P<0.0001). From period I to period II, there was a decreasing trend for mortality (from 0.64 to 0.53; P=0.1031) and median LOS (by 1 day; P=0.8293), without statistical significance.

Conclusions Implementing a risk-stratified intervention strategy may be a target-sensitive, convenient means to improve surgical outcomes.

Strengths and limitations of this study

- We developed a risk-stratified intervention strategy that covered the entire surgical pathway and evaluated its effectiveness among 51 030 inpatients in a multicentre prospective study in China.
- The contents of the intervention strategy focused on both regulating medical practices and managing inherent patient-related risks.
- The availability of the data limited our analysis to in-hospital complications, which may have contributed to their relatively low incidence.

INTRODUCTION

Surgical operations are complex, high-risk procedures.[1 2] At least seven million patients develop significant surgical complications worldwide each year, including one million perioperative deaths[3] (at least half of which are preventable[4]). During the last two decades, a series of safety-improvement interventions targeting technical and non-technical aspects have been proposed to strengthen surgical safety, such as hand-hygiene campaigns, pay-for-performance, teamwork training interventions and 'Lean' quality improvement programmes.[1 2 4–8]

Among these interventions, the 19-item WHO operating room surgical safety checklist (SSC), first proposed in 2008, is a prominent example of a widely implemented surgical intervention.[9] More than 100 countries worldwide have hospitals registered as participating sites that intend to introduce the WHO SSC into their operating rooms.[10] Several studies indicate that SSC has the potential to improve surgical outcomes,[11 12] whereas others state that this tool is not as effective as hoped because the common sense items and processes of care on the SSC seem unrelated to the most common serious complications.[13 14] The results of applying the WHO checklist in 101 Canadian hospitals is a real-life example of this observation.[15]

It is estimated that more than half of all surgical errors occur outside the operating room.[16 17] SURgical PAtient Safety System (SURPASS), another SSC, was developed to cover the entire surgical pathway, and its effectiveness has been validated.[6] SURPASS involves all aspects of surgical care and requires that 11 forms (~100 items) be completed and documented by numerous providers for each surgical patient.[18] Although this interventional strategy could regulate clinical practices of healthcare staff throughout the entire surgical pathway, it requires a heavy workload in the complex clinical setting, which undermines its adoption and compliance by frontline healthcare staff.[19]

Aware of these barriers, we surmised that a stratified, targeted intervention for surgical patients is more likely to be successful if its features were both target-sensitive and labour saving. Therefore, we developed a risk-stratified intervention strategy and implemented and evaluated its effectiveness for improving surgical outcomes in the Modern Surgery and Anaesthesia Safety Management System Construction and Promotion (MSCP) project in China.

METHODS

Data source

Data used in this study were obtained from the MSCP project, which was sponsored by the National Health and Family Planning Commission of China in 2014 to improve the safety of surgical patients. The MSCP project established a surgical information system that integrates surgical outcome reporting, clinical practice evaluation and perioperative safety interventions. More detailed information of the project has been published as a study protocol.[20] In the present study, we included data from four academic and teaching hospitals, representing the geographic and cultural diversity of the main Chinese administrative regions. The included hospitals were Peking Union Medical College Hospital; First Hospital of China Medical University; Qinghai Provincial People's Hospital; and Xiangya Hospital, Central South University.

Study design

To construct a risk-stratified intervention strategy and evaluate its effectiveness in improving the outcomes of surgical patients, we conducted two parallel preintervention and postintervention surveys. Period I (January to June 2015) had the primary purpose of acquiring empirical data to identify complication risk patterns and to develop a risk-stratified intervention strategy. Period II (January to June 2016) had the primary purpose of conducting the interventions and evaluating their effectiveness.

Participants

The surgical specialties involved were urological, orthopaedic, general, vascular, neurosurgery, and thoracic and cardiac surgery. The eligibility criteria included surgical (elective or emergent) inpatients, aged ≥14 years, with a hospital stay of ≥24 hours, who had undergone a procedure that required an anesthesiologist.

Outcome measures

The primary outcomes included death (during the hospital stay or confirmed within 30 days after discharge) and surgical complications in the hospital. We chose length of stay (LOS) as a secondary outcome, which is a critical marker for medical resource consumption and provides information on improving quality of surgical care.[21]

Covariates

Covariates included demographic characteristics (sex, age), smoking status, body mass index (BMI), American Society of Anesthesiologists (ASA) score, serum albumin and haemoglobin levels. Comorbidities included diabetes, hypertension, lung disease (chronic bronchitis, emphysema, pulmonary heart disease) and coronary heart disease. We also collected data on operative features that were likely to be associated with outcomes, including surgical specialty, emergency status and type of anaesthesia (general, regional).

All variables were collected via surgical information system and were submitted by the surgeons and nurses in charge within 1 week of patient discharge.

Quality control

This project involved >4000 participating medical staff, and multiple mechanisms that were applied to ensure the quality of the data.

1. *Presidents* (in charge of medical services) of the participating hospitals were coprincipal investigators in the project. They were directly responsible for supervising the process of the project, coordinating activities of various departments and communicating with the various centres to ensure that the actions of the four hospitals were operating within a unified standard framework.
2. *Head nurses* were the backbone force for quality control. They were responsible for verifying the data and reminding the rest of the staff about the implementation of the intervention activities. These reminders became an important duty in the daily morning meeting. The head nurses were competent for this role because they have high prestige in clinical practice, including among young doctors in China.
3. *Regular quality control measures* were also implemented, including double-entry checks, automatic logical verification, data monitoring (two times per month), random spot checks by a third party (every 2–3 months) and outcome inspection by specialist groups

(whenever necessary). A hotline was also available for the clinical staff in case of any questions about implementation. These activities were all supported by the project's funding.

Constructing the risk-stratified interventions

We constructed a risk-stratified intervention strategy using the following main steps. We underwent three rounds of a Delphi-like expert consensus process that resulted in 65 complication items to report (online supplementary table S1). Of these, 40 were selected and grouped into three categories according to three key features: incidence, severity and preventability. The three categories was considered targets in developing an intervention scheme, and included (1) common complications (23 items, including infections and wound complications, which were prevalent in all surgical categories); (2) specific complications (3 items including urinary tract infection, venous thrombosis and pulmonary embolism, which were more prevalent in some specific surgical categories); and (3) serious complications (14 items, in-hospital or confirmed death, cardiac arrest, respiratory failure and 8 others considered life-threatening when compared with the other complications). The remaining 25 items were combined in an 'other' complication category and remained untargeted in this study because most were technical complications[22] with an incidence too low to warrant exploring the regularity. Corresponding risk factors of the three targeted complications categories were identified and quantified to generate practical patterns for grading the risk of patients (as detailed in the study protocol).[20]

Based on this step, prevention methods (including risk assessment, basic tests, physical and medical prevention, regulations and core reminders, and diagnosis and treatment of systemic diseases, among others) were collected from front-line senior surgeons and nurses in the participating hospitals summarised as a 44-page document. The methods were then subjected to multidisciplinary group discussions in project meetings for further refinement.

Stratified interventions

Online supplementary table S2 shows the details of the safety interventions. Patients presenting any relevant risk factors (identified through data analysis and expert consensus) were targeted by at least one of the following interventions.

1. Generic interventions primarily targeted common complications. Standardised safety practices were required of all surgical staff members to implement the basic intervention strategy, especially for preventing surgical-site infection and pneumonia among patients presenting risk factors such as smoking and anaemia, among others.
2. Specific interventions targeted specific complications. Established prophylactic approaches were taken in patients at high risk of developing urinary tract infection and thrombosis, especially those undergoing urological or orthopaedic surgeries.
3. Intensive interventions targeted serious complications. Patients presenting with systemic diseases were further grouped by their risk level (mainly based on ASA score; see online supplementary table S2 for more details of the rules for classification) and recommended to undergo specific examinations and treatment of any preoperative diseases before and after surgery. We also performed internal consultations for those aged ≥65 years who had an ASA score of ≥3.

For most of these interventions, we only required the basic principles but left the choice for specific actions open; we did not intend to impose undue restrictions on surgeons' decisions.

System implementation and assessment of compliance

To make systematic implementation of the interventions more feasible, the intervention strategy was integrated into a risk-stratified perioperative checklist information system (RSC) as a routine part of clinical workflow. The doctors and nurses in charge were responsible for executing the system. The detailed process was as follows: after a patient was admitted, doctors were required to complete the preoperative risk assessment and patient workup, then use the checklist when prescribing medical orders. The doctors and nurses were automatically reminded to perform corresponding interventions in accordance with the specific information for that patient. The final check was submitted the day that the patient was discharged. The compliance rate for the medical staff regarding interventions was defined as follows: the number of patients with a preventive measure/the number of patients who presented with the relevant risk.

Ticking off the box in the checklist system was regarded as verification that the relevant intervention had been delivered. A specialised assessment of an intervention was not considered feasible in such a large-scale study.

Strategies for clinical engagement

The promotion of a safety culture while implementing the RSC is also considered an important element in this project. In this study, we strived to maximise the benefits of the RSC via the following strategies.

1. The formulation of all intervention measures was carried out with the guidance of 'complications pattern' according to the collective wisdom of the medical staff, rather than a few experts, thus making front-line staff aware of their responsibility.
2. Education and training were performed in each department—events that illustrated the appropriate checking practice and timing and, more importantly, clarified the interests of both patients and medical staff. In addition, system engineers went to each department to demonstrate how to operate the system, during which process the medical staff expressed great interest in identifying high-risk patients within the shortest time using the system.

3. We adopted a gradual strategy for introducing the RSC, starting with the operating room checklist.[23] This process enhanced the medical staff's belief in the system, making it seem natural to expand its use to cover perioperative interventions.

Statistical analysis

Because of the low incidence of surgical complications, each participating hospital was analysed as a covariate (not a stratification factor) to ensure the stability of incidence. Patient-level data used for risk adjustment were age, sex, ASA score, surgical category and study site.

To compare patients' characteristics between the two periods, we used Student's t-test for normally distributed variables, χ^2 test for categorical variables and Wilcoxon's rank test for ordinal variables and non-normally distributed variables. Unconditional logistic regression was used to explore the relationships between surgical complications in the three targeted categories and potential risk factors, with adjusted ORs and 95% CIs. The choices of potential risk factors for the regression analysis were based on the results of univariate analysis, with P<0.10 as the criterion for inclusion. Because various surgical complications may occur simultaneously in individual patients, a zero-inflated negative binomial regressions model was fitted to estimate the mean numbers of targeted complications per 100 patients, stratified by the complication categories. We used P values and incidence differences (95% CIs) to quantify the intervention's effects on surgical complications.

All statistical analyses were performed using SAS V.9.3 software. Statistical significance was set at P<0.05.

Patient and public involvement

No patients were involved in the development or design of this study. The study results will be disseminated to participants via publications.

RESULTS

Altogether, 58 165 patients were included during the two study periods, with 51 030 included in the final analysis (23 413 during period I and 27 617 during period II), for a study eligibility rate of 87.7%. Reasons for exclusion were duplicate records (2873), terminated surgery (1307), no anesthesiologist present (2425), patient <14 years (354), hospitalisation <24 hours (137) and missing information on sex or age (39).

Basic patient characteristics

Table 1 shows the patients' basic characteristics during the two study periods. Patients' characteristics were generally similar, although we saw small differences in some of them. Overall, more than one-third of patients underwent general surgery, up to 90% with general anaesthesia and one-fifth had an ASA score of ≥3.

Spectrum of complications in period I

Overall, 2153 complications occurred among 23 413 patients, for a mean incidence per 100 patients of 9.20 (95% CI 8.51 to 9.88). For the four complication categories, the incidences were 4.03 (95% CI 3.70 to 4.36) for common complications, 0.50 (95% CI 0.41 to 0.59) for specific complications, 3.76 (95% CI 3.31 to 4.20) for serious complications and 0.91 (95% CI 0.78 to 1.03) for other complications.

Figure 1 shows the pattern of complications in the high incidence categories and the five most frequent complications for each surgical specialty. There is a trend towards a gradually increasing incidence among all categories. The highest incidence occurred for thoracic and cardiac surgery, with incidences of 5.29% (common), 9.76% (serious) and 18.01% (overall) complications. These rates were 2.27, 13.75 and 4.33 times higher, respectively, than the incidences of complications for urological surgery. Serious complications clustered in the categories of general, vascular, neurosurgery, and thoracic and cardiac surgery, together accounting for 90.34% of all serious complications. Pneumonia and surgical-site infection were among the top five complications for each surgical specialty. Overall, 72.00% of all urinary tract infections in this study were associated with urological and orthopaedic surgery.

Risk patterns of complications during period I

Table 2 shows the adjusted ORs of risk factors for the complication subgroups within each of the three complication categories. The pattern and magnitude of risk factors among the three categories varied in specific ways. Overall, an ASA score ≥3 was an important risk factor for almost every complication, especially those serious complications (all ORs ≥5.0, all P<0.05), with an 11.42 times higher risk for death compared with deaths for lower scores (P<0.0001). Patients with an albumin level of <30 g/L had at least a twofold higher risk for each complication category. BMI ≥28 kg/m^2 increased the risk of surgical-site infection only compared with the lower BMI group (<24 kg/m^2). Older age was related to both specific and serious complications. For example, results showed an OR of 3.47 for urinary tract infection and 2.56 for cardiocerebrovascular events (CCV) in patients aged ≥65 years, compared with those aged <45 years. Comorbidities were strongly associated with serious complications. For example, patients with coronary heart disease had an 8.30 times higher risk of CCV than those with no such disease (P<0.0001). These estimates created the rationale for stratified safety interventions.

Interventions during period II

Altogether, 21 630 (78.3%) surgical patients during period II were entered in the RSC system. Among these patients, 8857 (41.0%) were classified into the specific intervention group, 6688 (30.9%) into the intensive intervention group. Doctors' and nurses' compliance rates are shown in the supplementary material, stratified by surgical specialty (online supplementary table S3) and major risk measures (online supplementary table S4). Overall, at least one intervention measure (excluding generic

Table 1 Patient characteristics in the two study periods

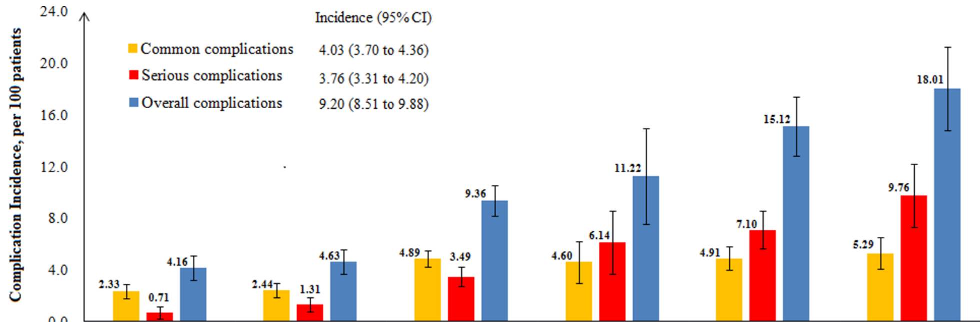
Characteristics	Total	Period I	Period II	P value
No	51 030	23 413	27 617	
Male, n (%)	26 346 (51.6)	12 074 (51.6)	14 272 (51.7)	0.8066
Age (years), mean (SD)	52.0 (15.1)	51.7 (15.1)	52.3 (15.1)	<0.0001
Age group, n (%)				0.0001
<45	14 576 (28.6)	6880 (29.4)	7696 (27.9)	
45~	12 654 (24.8)	5778 (24.7)	6876 (24.9)	
55~	13 442 (26.3)	6165 (26.3)	7277 (26.4)	
65~	10 358 (20.3)	4590 (19.6)	5768 (20.9)	
BMI (kg/m^2), n (%)				0.1779
<24	27 277 (53.8)	12 485 (53.7)	14 792 (53.9)	
24~	17 540 (34.6)	7998 (34.4)	9542 (34.7)	
28~	5907 (11.7)	2774 (11.9)	3133 (11.4)	
Current smoking, n (%)	6982 (13.7)	3426 (14.6)	3556 (12.9)	<0.0001
Comorbidities, n (%)				
Hypertension	19 513 (38.2)	9046 (38.6)	10 467 (37.9)	0.0882
Diabetes	3986 (7.8)	1804 (7.7)	2182 (7.9)	0.4114
Coronary heart disease	2657 (5.2)	1234 (5.3)	1423 (5.2)	0.5501
Lung disease	632 (1.2)	332 (1.4)	300 (1.1)	0.0007
Preoperative laboratory test				
Albumin <30 g/L, n (%)	1467 (3.0)	666 (3.0)	801 (3.0)	0.9437
Haemoglobin <100 g/L, n (%)	2777 (5.7)	1256 (5.6)	1521 (5.7)	0.6265
ASA score, n (%)				<0.0001
1	12 073 (24.4)	5881 (25.5)	6192 (23.4)	
2	25 621 (51.7)	11 505 (49.9)	14 116 (53.3)	
3	10 119 (20.4)	4757 (20.6)	5362 (20.2)	
≥4	1750 (3.5)	909 (3.9)	841 (3.2)	
Surgical category, n (%)				0.0021
General surgery	19 505 (38.2)	9058 (38.7)	10 447 (37.8)	
Vascular surgery	2171 (4.3)	1043 (4.5)	1128 (4.1)	
Urological surgery	8466 (16.6)	3944 (16.9)	4522 (16.4)	
Thoracic and cardiac surgery	4967 (9.7)	2193 (9.4)	2774 (10.0)	
Neurosurgery	6240 (12.2)	2831 (12.1)	3409 (12.3)	
Orthopaedic surgery	9681 (19.0)	4344 (18.6)	5337 (19.3)	
Emergency, n (%)	2959 (6.2)	1369 (6.3)	1590 (6.2)	0.4130
General anaesthesia, n (%)	42 275 (91.3)	18 521 (90.2)	23 574 (92.1)	<0.0001

ASA, American Society of Anesthesiologists; BMI, body mass index (weight/height^2, kg/m^2).

prevention, which was applied to all surgical staff) was delivered to 75.3% of patients preoperatively and 66.6% postoperatively. In general, the rate of compliance in use of the preoperative checklist was higher than that of the postoperative checklist (54.8% vs 38.2%) for doctors, whereas the rates among nurses were stable during the two stages (53.4% vs 53.6%). There was relatively higher compliance with our recommendation for cardiac risks (57.4%) than for other intensive intervention measures in high-risk patients.

Evaluation of intervention effect

Overall, 2153 and 2119 complications occurred during the two study periods, respectively. After adjustment, we observed a significant decrease in the mean number of overall complications per 100 patients: from 8.84 (95% CI 8.72 to 8.97) during period I to 7.56 (95% CI 7.46 to 7.66) during period II (P<0.0001) (table 3). The relative risk differences for common, specific and serious complications were 7.8% (P=0.0677), 28.0% and 20.9% (both P<0.05), respectively. The relative risk difference



Most Frequent Complications	Urology	Orthopeadics	General surgery	Vascular surgery	Neurosurgery	Thoracic and cardiac surgery
1	Urinary system infection, 0.96%	Delayed or non-union wound, 0.92%	Surgical site infection, 1.69%	Delayed or non-union wound, 1.44%	Pneumonia, 2.97%	Postoperative mechanical ventilation ≥ 48 hours, 2.46%
2	Delayed or non-union wound, 0.91%	Surgical site infection, 0.71%	Delayed or non-union wound, 0.96%	Pneumonia, 1.15%	Postoperative mechanical ventilation ≥ 48 hours, 2.33%	Pneumonia, 2.33%
3	Surgical site infection, 0.58%	Pneumonia, 0.48%	Pneumonia, 0.91%	Renal Failure, 0.96%	Central high fever, 0.78%	Atelectasis, 1.69%
4	Haemorrhage requiring ≥4 U red blood cell infusion 72hours postoperatively, 0.23%	Urinary system infection, 0.37%	Postoperative mechanical ventilation ≥ 48 hours, 0.53%	Myocardial infarction, 0.86%	Delayed or non-union wound, 0.74%	Delayed or non-union wound, 1.19%
5	Pneumonia, 0.18%	Postoperative mechanical ventilation ≥ 48 hours, 0.30%	Respiratory failure, 0.46%	Surgical site infection, 0.77%	Respiratory failure, 0.57%	Heart failure, 1.14%

Figure 1 Spectrum of complications during period I and most frequent complications for each surgical specialty. See online supplementary table S1 for definitions and complication categories.

for mortality was 17.2% (0.64% vs 0.53%, respectively; P=0.1031). For the other complications category, there was a 9.9% relative risk decrease but with no significant difference (P=0.2729). Overall, the complication incidences fluctuated between 7.2 and 7.9 per 100 patients during the 6-month postintervention period, with no temporal trends (P>0.05) in outcomes in any surgical category.

The median LOS decreased by 1 day (from 12 to 11 days) from period I to period II, with no statistical significance (P=0.8293).

Subgroup analysis

Figure 2 shows the adjusted incidence of complications during period II and the incidence difference (95% CI) between the two periods, by surgical specialty. There was a marked decrease from period I to period II for complications associated with thoracic and cardiac surgery and general surgery. For example, the mean number of complications per 100 patients in the thoracic and cardiac surgery group with common, serious and overall complications decreased by 1.75, 4.49 and 6.06, respectively (all P<0.05). There was a similar trend for vascular surgery regarding common and overall complications, with the mean number per 100 patients decreasing by 2.70 and 2.77, respectively. There was, however, no significant difference for urological surgery or neurosurgery.

DISCUSSION

To the best of our knowledge, this study represents the first attempt to develop and evaluate a risk-stratified, perioperative intervention strategy, that is, focused directly on both medical staff and patient factors with the goal of reducing surgical complications. The study was carried out in four representative hospitals in China, and the results were encouraging. The mean number of overall complications per 100 patients decreased from 8.84 to 7.56 from period I to period II, with similar trends in reducing common, specific and serious complications. Although the 17.2% relative reduction in mortality and the 1 day reduction in median LOS were not statistically significant, these trends could be critical both clinically and economically if confirmed by further studies.

Four major considerations validated the results in this study. First, any seasonal variation in patient outcome was neutralised by the timing of the two study periods (January to June during both 2015 and 2016).[24] Second, the medical profession is a full-time occupation in China, so the staff composition was quite stable, contributing to constant safety improvement. Third, patients' socioeconomic status was similar across the two study periods in each hospital because of the medical insurance policy in China.[25] Fourth, the large study sample stabilised the incidence of complications and increased the validity of the study results.

'Generic intervention' was the priority of our strategy, which stresses regulating basic safety practices for all medical staff. In fact, the most frequent 'common complication' in this study was infection. The high levels of infections across all surgical specialties were similar to findings of other studies,[4 6 26] reinforcing the rationale for the prevention of infection as a worldwide priority for patient safety.[27–29] In 2005, the 'clean care is safer care' campaign was launched by the WHO as the first step in the global patient safety challenge,[30] and dedicated tools to counter infection prevalence have been

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Table 2 OR and 95% CI of risk factors for complications using period I data

Risk factors	Common complications: SSI	Pneumonia	BSI	WC	OI	Specific complications: Thrombosis	UTI	Serious complications: CCV	OD	OSC	Death
Male*	2.39 (1.79 to 3.20)	1.57 (1.20 to 2.05)	2.25 (1.40 to 3.61)	1.51 (1.15 to 1.98)	4.62 (2.22 to 9.59)				2.02 (1.41 to 2.87)	1.63 (1.25 to 2.14)	1.62 (1.14 to 2.31)
Aged 45~ years†					2.30 (1.09 to 4.83)						
Aged 55~ years†						5.44 (1.53 to 19.32)			1.79 (1.06 to 3.03)		
Aged 65~ years†		2.73 (1.90 to 3.91)				7.05 (1.97 to 25.24)	3.47 (1.70 to 7.09)	2.56 (1.37 to 4.79)	2.61 (1.56 to 4.37)		2.32 (1.40 to 3.85)
Obese‡	1.54 (1.03 to 2.30)										
Current smoking§								1.98 (1.19 to 3.27)			1.54 (1.01 to 2.34)
Albumin <30 g/L¶	2.78 (1.80 to 4.29)	2.32 (1.47 to 3.64)	4.11 (2.07 to 8.15)	2.97 (1.91 to 4.61)	2.97 (1.13 to 7.76)	5.73 (2.06 to 15.98)		5.08 (2.62 to 9.86)	3.47 (2.05 to 5.88)	3.64 (2.38 to 5.56)	5.85 (3.47 to 9.87)
Haemoglobin <100 g/L**	1.79 (1.17 to 2.75)			1.93 (1.26 to 2.97)		2.73 (1.02 to 7.32)		2.84 (1.49 to 5.41)	1.80 (1.04 to 3.13)	2.38 (1.57 to 3.60)	2.75 (1.53 to 4.92)
Hypertension††		1.48 (1.11 to 1.98)				2.68 (1.20 to 5.97)		1.80 (1.11 to 2.93)		1.59 (1.19 to 2.12)	1.48 (1.03 to 2.12)
Diabetes††								3.12 (1.14 to 8.55)			
Coronary heart disease††								8.30 (3.47 to 19.82)		2.37 (1.11 to 5.08)	2.56 (1.06 to 6.19)
Lung disease††								4.79 (1.42 to 16.20)			
Any of two above††		1.66 (1.05 to 2.64)		1.87 (1.18 to 2.96)					2.86 (1.77 to 4.60)	2.49 (1.64 to 3.78)	
Any of three or more††								3.17 (1.05 to 9.57)	3.99 (1.76 to 9.03)	2.90 (1.33 to 6.32)	
ASA score ≥3‡‡	2.38 (1.72 to 3.31)	3.24 (2.34 to 4.50)	8.73 (5.08 to 15.02)	2.12 (1.51 to 2.97)		2.74 (1.24 to 6.05)		5.52 (3.36 to 9.05)	10.18 (6.82 to 15.19)	12.03 (8.69 to 16.65)	11.42 (7.01 to 18.59)

All analyses were adjusted by age, sex, American Society of Anesthesiologists score, surgical category and participating hospital.
See online supplementary table S1 for definitions and categorisation of complications.
*Female as reference.
†Aged 14–44 years as reference.
‡Obese: body mass index ≥28 kg/m^2, body mass index <24 kg/m^2 as reference.
§Non-current smoker as reference.
¶Albumin ≥30 g/L as reference.
**Haemoglobin ≥100 g/L as reference.
††Patients without hypertension, diabetes, coronary heart disease and lung disease as reference.
‡‡American Society of Anesthesiologists score <3 as reference.
BSI, blood stream infections; CCV, cardiocerebrovascular events; death, inpatient/confirmed death; OD, organ dysfunction; OI, other infections; OSC, other serious complications; SSI, surgical site infection; UTI, urinary tract infections; WC, wound complications.

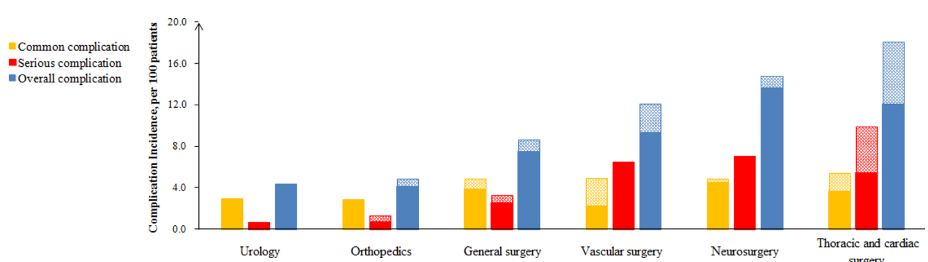
Table 3 Comparison of complications incidences between the two study periods

Complications	Period I (per 100 patients)	Period II (per 100 patients)	Relative risk difference (%)	P value for comparison
Overall complications	**8.84**	**7.56**	**14.48**	**<0.0001**
Common complications	**3.96**	**3.65**	**7.83**	**0.0677**
Surgical site infection	1.04	0.79	24.04	0.0030
Pneumonia	1.08	1.06	1.85	0.8267
Blood stream infections	0.54	0.38	29.63	0.0073
Wound complications	1.12	1.13	–	0.7489
Other infections	0.25	0.24	4.00	0.8197
Specific complications	**0.50**	**0.36**	**28.00**	**0.0153**
Thrombosis	0.18	0.18	–	0.7906
Urinary tract infection	0.33	0.18	45.45	0.0007
Serious complications	**3.64**	**2.88**	**20.88**	**<0.0001**
Cardiocerebral vascular events	0.47	0.34	27.66	0.0204
Organ dysfunction	1.04	0.74	28.85	0.0003
Others serious complications	1.56	1.29	17.31	0.0100
Inpatient/confirmed death	0.64	0.53	17.19	0.1031
Other complications	**0.91**	**0.82**	**9.89**	**0.2729**

All analyses were adjusted by age, sex, American Society of Anesthesiologists score, surgical category and participating hospital.
See online supplementary table S1 for definitions and complication categories.
Figures in bold fonts represent information of overall complication and the four comlication categories we classifed in this study.

in existence for some time.[29 31] Nevertheless, there is still a gap between knowledge and implementation of these basic patient safety measures,[32] especially considering the heavy burden associated with the high volume of surgical patients in China. In our strategy, we emphasised three key points: (1) transfer the use of antibiotics from the ward to the operating room to ensure they are administered within 30–60 min before incision; (2) surgeons' hands must be carefully scrubbed for 2–6 min following standard procedures; (3) nutritional support should be available, particularly for anaemic patients. Each of these criteria was integrated into the RSC of this study to ensure its implementation in daily clinical practice.

Evidence-based methods are also available in several guidelines to prevent specific complications such as thrombosis and urinary tract infection.[27 33 34] Our data indicated that these two complications occurred mainly with urological and orthopaedic surgery. Therefore, we identified high-risk patients and implemented 'specific interventions' to increase efficiency. The effectiveness of



	Urology	Orthopedics	General surgery	Vascular surgery	Neurosurgery	Thoracic and cardiac surgery
Common complication						
period II (incidence per 100 patients)	2.95	2.89	3.88	2.26	4.50	3.66
Difference between period I and periond II	-0.62 (-1.30 to 0.06)	-0.26 (-0.91 to 0.39)	0.96 (0.38 to 1.54)	2.70 (1.12 to 4.28)	0.38 (-0.68 to 1.44)	1.75 (0.57 to 2.93)
P value	0.0770	0.4384	0.0010	0.0007	0.4789	0.0029
Serious complication						
period II (incidence per 100 patients)	0.65	0.73	2.54	6.46	7.06	5.42
Difference between period I and periond II	-0.02 (-0.36 to 0.32)	0.54 (0.14 to 0.94)	0.70 (0.23 to 1.17)	-0.22 (-2.27 to 1.83)	-0.20 (-1.47 to 1.07)	4.49 (2.98 to 6.00)
P value	0.9084	0.0071	0.0035	0.8337	0.7574	<0.0001
Overall complication						
period II (incidence per 100 patients)	4.37	4.14	7.51	9.28	13.62	12.03
Difference between period I and periond II	-0.25 (-1.11 to 0.61)	0.68 (-0.15 to 1.51)	1.09 (0.32 to 1.86)	2.77 (0.17 to 5.37)	1.12 (-0.62 to 2.86)	6.06 (4.04 to 8.08)
P value	0.5696	0.1064	0.0052	0.0363	0.2060	<0.0001

Figure 2 Comparison of complication incidences during the two study periods, by surgical specialty. Solid bar chart indicates the complication incidences during period II. Dotted shadow represents the complication incidence differences between period I and period II. All analyses were adjusted by age, sex, American Society of Anesthesiologists score and participating hospital.

these interventions for preventing urinary tract infections was validated in our results. However, we saw no significant difference for thrombosis between preintervention and postintervention, which may be attributed to two factors: (1) certain sensitive thrombosis surveillance tools (eg, imaging) were not routinely used in the participating hospitals, especially in asymptomatic patients; and (2) the hospitals had conducted several education modules on thrombosis prevention in these specialties prior to our study.

Regarding the prevention of serious complications, previous efforts focusing on minimising medical errors have generally paid less attention to inherent patient-related risks. In contrast, emerging evidence[35–37] and our results strongly suggest that patient factors are the primary cause of poor outcomes. Hence, we instituted an 'intensive intervention' in our study that focused primarily on the management of patient-related risks (especially systemic diseases) using a relatively simple but comprehensive ASA score. First and foremost, ASA score was assessed by the doctors in charge shortly after the patients was admitted to the ward, rather than by the anesthesiologists alone, which intensified patients' preoperative management. Also, a patient with ASA score of ≥3 was highlighted and that information was transferred throughout the surgical pathway to alert all medical staff of the patient's higher risk. We also stressed multidisciplinary consultation for patients aged ≥65 years and with an ASA score ≥3. The effectiveness of these strategies was well validated by our results. For example, relatively high compliance was observed regarding our recommendation of internal medicine consultation for cardiac risks, and the overall reduction in the number of CCV was as high as 27.7%. These findings not only indicate the sensitivity of our intervention indicators but also emphasise that patient safety is a systematic consideration that takes into account how well the needed measures are carried out in daily clinical practice—rather than considering safety a purely medical technical issue.

Compared with SURPASS, which requires that all items be checked for each patient regardless of necessity,[19] we adopted a risk-stratified strategy using the RSC platform to deliver necessary safety interventions to those patients most in need. Thus, we achieved high implementation efficiency by reducing operational complexity, which was the key to successful buy-in among the medical users. Another benefit of using the present information system was the seamless chain of information flow,[38] in which the transfer of key patient information helped strengthen cooperation among professions, stages and divisions for the same patient.[37] Moreover, using the RSC, long-lasting mechanisms can be established to shape standard medical customs and promote a 'safety culture'.[38–40] This principle especially applies to novice surgeons, who can start learning from both the system and their tutors at the beginning of their careers.

It should be emphasised that the development of a safety culture is a long-term endeavour and cannot be achieved with only one or two projects. Compliance with our interventions were not ideal; in 2017, we saw a trend towards decreasing interest, as with other projects, which is a global challenge.[18] There is no doubt, however, that research activities play a major role in promoting cognitive improvement and changes that can create a culture of safety.

Limitations and challenges remain. First, although the complications reported in this study were similar to those reported from 101 hospitals in Canada and 28 hospitals in the USA,[15 41] our complication rates were lower than those in some other reports.[4 6] This discrepancy stems mainly from two aspects. (1) We limited the collection of complication-related data to the duration of hospital stay, rather than reporting complications that occurred within 30 days postoperatively. Collecting accurate information on patients' complications after discharge from the hospitals by conducting large-scale follow-up was challenging in our study. (2) Concern over blame and repercussions has traditionally led to underreporting of surgical complications.[42] Second, although we consider that the secular trend associated with economic and technical development was small in our short study period, and there were too few coexisting safety programmes in China to have a contamination effect, the lack of contemporary control hospitals is a limitation to the validity of our results, especially regarding the outcomes of low incidence. Third, the compliance rates with the interventions were self-reported and thus are subject to bias[23]; the suboptimal rates among medical staff members strongly indicate that further enhancement of implementation quality is needed. In addition, we did not specifically focus on the other complications. These complications therefore remain safety targets to be addressed in the future.

In conclusion, implementing a risk-based stratified intervention strategy was associated with a wide-scale reduction in surgical complications at four Chinese hospitals with high patient volumes. To achieve better surgical outcomes, efforts should be made to both standardise medical care and mitigate patient-related risks in a target-sensitive, convenient manner.

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