



Compliance with the Surviving Sepsis Campaign guideline 1-hour bundle for septic shock in China in 2018

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Background: Effective implementation of the Surviving Sepsis Campaign (SSC) guidelines has effectively reduced sepsis mortality. The effects of hospital level and ownership on compliance with the SSC guideline 1-hour bundle (C_{SSC-1h}) are unclear. We designed this study to identify the differences in C_{SSC-1h} between secondary and tertiary hospitals, public hospitals, and private hospitals.

Methods: In this survey, 1,420 hospitals were enrolled, including 864 public tertiary hospitals, 482 public secondary hospitals, 34 private tertiary hospitals, 40 private secondary hospitals. The data were collected between January 1, 2018, and December 31, 2018. The outcomes were adherence to the SSC guidelines (2018 update). Monitoring indicators include 1-hour bundle and its sub-indicators (measure lactate level and remeasure lactate level if initial lactate is >2 mmol/L, obtain blood cultures before administering antibiotics, administer broad-spectrum antibiotics, begin rapid administration of 30 mL/kg crystalloid for hypotension or lactate ≥ 4 mmol/L, apply vasopressor if hypotension is present during or after fluid resuscitation to maintain a mean arterial pressure ≥ 65 mmHg). Every monitoring indicator was stratified by the median, which is defined as 1 if greater than or equal to the median, and 0 if not.

Results: C_{SSC-1h} in tertiary hospitals was significantly higher than in secondary hospitals ($P < 0.05$). However, there were no statistical differences in C_{SSC-1h} in public hospitals and private hospitals.

Conclusions: C_{SSC-1h} in tertiary hospitals was significantly better than that in secondary hospitals. There is an urgent need to improve C_{SSC-1h} in secondary hospitals. The increase in private hospitals will not reduce C_{SSC-1h} .

Keywords: Saving Sepsis Campaign guidelines; tertiary hospitals; secondary hospitals; public hospitals; private hospitals

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Introduction

Sepsis-3 is defined as the downregulation of host response after infection and the occurrence of life-threatening organ dysfunction, which is an important cause of death (1).

Septic shock is a serious condition in sepsis development, with abnormal circulation and metabolism (2). Even with active fluid resuscitation, persistent hypotension can occur and be life-threatening due to a combination of

severe vasodilatation, low catecholamine reactivity, and myocardial inhibition in septic shock (3). Sepsis has become the most-watched disease in critical care medicine due to its high morbidity and mortality (4). The “sepsis bundle” has been central to the implementation of the Surviving Sepsis Campaign (SSC) from the first publication of its evidence-based guidelines in 2004 (5-8). The evidence in the literature has demonstrated an association between compliance with bundles and improved survival in patients with sepsis and septic shock (9-11). To improve compliance with bundles, the SSC revised their care bundle in 2018 (12). Unlike the 3-hour and 6-hour bundle recommended in their 2016 guidelines (8), the 2018 update recommends completing the sepsis bundle within 1 hour (12).

Hospitals in China are classified into 3 levels. Primary hospitals rarely admit and treat patients with septic shock. Secondary hospitals are the main body of diagnosis and provide treatment for septic shock. Tertiary hospitals are medical technology centers in China. The main function of tertiary hospitals is to provide specialized medical services to solve critical and difficult diseases. According to ownership, hospitals in China are classified into public hospitals and private hospitals. With the adjustment of medical policies, private hospitals play an increasingly important role in diagnosing and treating septic shock. Whether there is a difference in compliance with SSC guideline 1-hour bundle ($C_{\text{SSC-1h}}$) between secondary and tertiary hospitals, public hospitals, and private hospitals has not been reported in the literature. Therefore, we conducted this survey to identify the differences in $C_{\text{SSC-1h}}$ between secondary and tertiary hospitals, public hospitals, and private hospitals to improve the prognosis of patients with sepsis. We present the following article following the Materials Design Analysis Reporting (MDAR) reporting checklist (available at <http://dx.doi.org/10.21037/atm-20-5429>).

Methods

Study design

In this survey, 1,420 hospitals were enrolled in the Quality Improvement of Critical Care Program, led by the China National Critical Care Quality Control Center. These comprised 864 public tertiary hospitals, 482 public secondary hospitals, 34 private tertiary hospitals, 40 private secondary hospitals. These hospitals admitted 143,616 patients with septic shock, of which public tertiary hospitals

admitted 108,696 patients, public secondary hospitals admitted 31,197 patients, private tertiary hospitals admitted 1,975 patients, and private secondary hospitals admitted 1,748 patients. Data were collected between January 1, 2018, and December 31, 2018. Informed consent was obtained from every hospital participating in the study. All information on the participating hospitals is listed in *Tables 1* and *2*.

The outcomes were adherence to the SSC guidelines (2018 update). Monitoring indicators included the 1-hour bundle and its sub-indicators (measure lactate level and remeasure lactate level if initial lactate is >2 mmol/L, obtain blood cultures before administering antibiotics, administer broad-spectrum antibiotics, begin rapid administration of 30 mL/kg crystalloid for hypotension or lactate ≥ 4 mmol/L, apply vasopressor if hypotension is present during or after fluid resuscitation to maintain a mean arterial pressure ≥ 65 mmHg). Every monitoring indicator was stratified by the median, defined as 1 if greater than or equal to the median, and 0 if not.

Based on the data obtained from this survey, we analyzed the effects of hospital level and ownership on $C_{\text{SSC-1h}}$ in septic shock in China. We then determined which medical quality indicators affected $C_{\text{SSC-1h}}$ in septic shock in China.

The study was conducted following the Declaration of Helsinki (as revised in 2013). The central institutional review board approved the trial protocol at Peking Union Medical College Hospital (No. S-K1297), and individual consent for this retrospective analysis was waived.

In all participating clusters, data were obtained and entered into a web-based data entry system by a local, trained independent research coordinator who was not involved in patient care and received compensation from this trial. Range checks were used to check for inconsistent or out-of-range data and prompted the user to correct or review data entries outside the predefined range. The system also provided predefined logic checks to identify errors or illogical data entries. A data-quality meeting was held monthly to review all the hospital enrollment records and registry data. The datasets supporting the conclusions of this article are included within the article and its additional files.

Statistical analysis

Statistical analysis was performed using SPSS 16.0 software (SPSS, Chicago, IL, USA). Basic information was expressed as mean \pm standard error of mean values and

Table 1 Basic information of tertiary and secondary hospitals

Variables	Tertiary hospitals	Secondary hospitals	P
Public hospitals			
Beds/ICU	27.86±34.71	12.14±6.99	<0.0001
Patients /ICU	1,212.54±1,717.63	559.97±510.99	<0.0001
Patients with septic shock/ICU	125.81±179.61	64.72±111.85	<0.0001
Private hospitals			
Beds/ICU	17.03±10.28	9.85±4.5	0.0005
Patients/ICU	661.18±432.08	364.7±256.82	0.0009
Patients with septic shock/ICU	58.09±37.65	43.7±30.18	0.0722

Table 2 Basic information of public and private hospitals

Variables	Public hospitals	Private hospitals	P
Tertiary hospitals			
Beds/ICU	27.86±34.71	17.03±10.28	<0.0001
Patients/ICU	1,212.54±1,717.63	661.18±432.08	<0.0001
Patients with septic shock/ICU	125.81±179.61	58.09±37.65	<0.0001
Secondary hospitals			
Beds/ICU	12.14±6.99	9.85±4.5	0.0048
Patients/ICU	559.97±510.99	364.7±256.82	<0.0001
Patients with septic shock/ICU	64.72±111.85	43.7±30.18	0.003

compared using the one-way analysis of variance test. $C_{\text{ssc-1h}}$ was expressed as median and quartile M (P25, P75), and compared using the rank test. Stratifications of $C_{\text{ssc-1h}}$ were expressed as 0 or 1, and compared using logistic regression. $P < 0.05$ was considered to be statistically significant.

Results

Effects of hospital level on $C_{\text{ssc-1h}}$

In public hospitals, except for the completion of empiric broad-spectrum therapy and completion of resuscitation with 30 mL/kg crystal liquid, most indicators of $C_{\text{ssc-1h}}$ in tertiary hospitals were significantly higher than those in secondary hospitals ($P < 0.05$). The same phenomenon was not observed in private hospitals (Table 3).

Effects of hospital ownership on $C_{\text{ssc-1h}}$

In both tertiary and secondary hospitals, all indicators of

$C_{\text{ssc-1h}}$ between public hospitals and private hospitals were not statistically different (Table 4).

Effects of hospital level and ownership on the stratification of $C_{\text{ssc-1h}}$

Stratification of $C_{\text{ssc-1h}}$ in tertiary hospitals was significantly higher than that in secondary hospitals ($P < 0.05$). However, there were no statistical differences in the stratification of $C_{\text{ssc-1h}}$ in public hospitals and private hospitals (Table 5).

Differences in medical quality index between tertiary hospitals and secondary hospitals

The nurse-to-patient ratio in the intensive care unit (ICU) and the proportion of total ICU inpatient bed occupancy in tertiary hospitals were significantly higher than that in secondary hospitals ($P < 0.05$). The same phenomenon was not observed in the doctor-to-patient ratio in the ICU

Table 3 Effects of hospital level on *C_{ssc-1h}*

Variables	Tertiary hospitals	Secondary hospitals	P
Public hospitals			
Hour-1 bundle	79.29 (54.48, 95.52)	72.55 (40.85, 95.24)	0.0034
Remeasure of lactate	88.57 (64.35, 100)	80.1 (46.88, 100)	<0.0001
Blood cultures	97.1 (78.04, 100)	86.36 (54.12, 100)	<0.0001
Broad-spectrum antibiotics	100 (91.73, 100)	100 (88.37, 100)	0.4324
30 mL/kg crystalloid	94.31 (79.45, 100)	92.45 (75.36, 100)	0.1929
Vasopressor	80 (57.6, 100)	68.3 (41.67, 93.75)	<0.0001
Private hospitals			
Hour-1 bundle	70.43 (47.83, 100)	70 (45.43, 97.37)	0.4364
Remeasure of lactate	72.64 (45.21, 100)	78.71 (53.13, 100)	0.5383
Blood cultures	97.87 (69.7, 100)	83.67 (54.57, 100)	0.393
Broad-spectrum antibiotics	100 (90.91, 100)	100 (76.94, 100)	0.1986
30 mL/kg crystalloid	90.75 (70.18, 100)	92.37 (70.5, 100)	0.8846
Vasopressor	75.8 (54.1, 100)	63.33 (48.11, 98.11)	0.2887

Remeasure of lactate = measure lactate level and remeasure lactate if initial lactate elevated (>2 mmol/L); blood cultures = obtain blood cultures before administering antibiotics; broad-spectrum antibiotics = administer broad-spectrum antibiotics; 30 mL/kg crystalloid = begin rapid administration of 30 mL/kg crystalloid for hypotension or lactate \geq 4 mmol/L; vasopressor = apply vasopressor if hypotension during or after fluid resuscitation to maintain a mean arterial pressure \geq 65 mmHg.

Table 4 Effects of hospital ownership on *C_{ssc-1h}*

Variables	Public hospitals	Private hospitals	P
Tertiary hospitals			
Hour-1 bundle	79.29 (54.48, 95.52)	70.43 (47.83, 100)	0.9474
Remeasure of lactate	88.57 (64.35, 100)	72.64 (45.21, 100)	0.1135
Blood cultures	97.1 (78.04, 100)	97.87 (69.7, 100)	0.8023
Broad-spectrum antibiotics	100 (91.73, 100)	100 (90.91, 100)	0.6174
30 mL/kg crystalloid	94.31 (79.45, 100)	90.75 (70.18, 100)	0.5611
Vasopressor	80 (57.6, 100)	75.8 (54.1, 100)	0.7775
Secondary hospitals			
Hour-1 bundle	72.55 (40.85, 95.24)	70 (45.43, 97.37)	0.9157
Remeasure of lactate	80.1 (46.88, 100)	78.71 (53.13, 100)	0.5091
Blood cultures	86.36 (54.12, 100)	83.67 (54.57, 100)	0.6096
Broad-spectrum antibiotics	100 (88.37, 100)	100 (76.94, 100)	0.2608
30 mL/kg crystalloid	92.45 (75.36, 100)	92.37 (70.5, 100)	0.7256
Vasopressor	68.3 (41.67, 93.75)	63.33 (48.11, 98.11)	0.9635

Remeasure of lactate = measure lactate level and remeasure lactate if initial lactate elevated (>2 mmol/L); blood cultures = obtain blood cultures before administering antibiotics; broad-spectrum antibiotics = administer broad-spectrum antibiotics; 30 mL/kg crystalloid = begin rapid administration of 30 mL/kg crystalloid for hypotension or lactate \geq 4 mmol/L; vasopressor = apply vasopressor if hypotension during or after fluid resuscitation to maintain a mean arterial pressure \geq 65 mmHg.

Table 5 Effects of hospital level and ownership on stratification of $C_{\text{ssc-1h}}$

Variables	Tertiary vs. secondary		Public vs. private	
	OR	95% CI	OR	95% CI
Hour-1 bundle	1.442	1.085–1.914	1.415	0.836–2.394
Remeasure of lactate	1.632	1.206–2.209	1.000	0.565–1.773
Blood cultures	2.032	1.442–2.863	0.765	0.391–1.497
Broad-spectrum antibiotics	2.259	1.385–3.684	0.999	0.404–2.473
30 mL/kg crystalloid	1.887	1.259–2.829	1.070	0.506–2.263
Vasopressor	1.715	1.285–2.289	1.071	0.619–1.852

Remeasure of lactate = measure lactate level and remeasure lactate if initial lactate elevated (>2 mmol/L); blood cultures = obtain blood cultures before administering antibiotics; broad-spectrum antibiotics = administer broad-spectrum antibiotics; 30 mL/kg crystalloid = begin rapid administration of 30 mL/kg crystalloid for hypotension or lactate ≥ 4 mmol/L; vasopressor = apply vasopressor if hypotension during or after fluid resuscitation to maintain a mean arterial pressure ≥ 65 mmHg.

and Acute Physiology and Chronic Health Evaluation (APACHE II) score ≥ 15 in all ICU patients (Table 6).

Discussion

There are at least 31.5 million sepsis patients worldwide, 19.4 million of whom have severe sepsis. More than 5 million patients died of sepsis every year (13). In the treatment of sepsis, effective implementation of SSC guidelines can reduce fatality and improve prognosis (9–11). To improve compliance with bundles, the SSC constantly updates their care bundle according to new evidence from the first publication in 2004. In 2018 the SSC launched 1-hour bundle (12). Unlike the 3-hour and 6-hour bundles that were recommended in the SSC 2016 guidelines (8), the 2018 update recommends completing the sepsis bundle within 1 hour (12). To improve $C_{\text{ssc-1h}}$ and the prognosis of patients with sepsis, the National Health Commission of China issued quality control requirements for critical care medicine in 2015, including sepsis treatment. However, $C_{\text{ssc-1h}}$ in Asia is still low at present (14). Educating medical staff on sepsis being a medical emergency and that it is important to implement guidelines effectively is still a problem. There are still some doctors in China, especially non-ICU doctors, who lack understanding of SSC guidelines, and many have many problems implementing the SSC guidelines. Wang *et al.* found that the implementation of SSC guidelines by emergency physicians is often hindered by doctors' awareness and attitude (15). In the present study, monitoring indicators were developed according to SSC

guideline 1-hour bundle to analyze differences in $C_{\text{ssc-1h}}$ in different types of hospitals in China in 2018 to strengthen the supervision of sepsis treatment and implement the SSC guideline 1-hour bundle more effectively. In the present study, we found that $C_{\text{ssc-1h}}$ in tertiary hospitals was significantly higher than that in secondary hospitals. However, there were no statistical differences in $C_{\text{ssc-1h}}$ in public hospitals and private hospitals.

In China, hospital qualifications are assessed according to hospital functions, facilities, technical strength, and other indicators. Hospital qualification assessment is unified across the country, regardless of hospital background or ownership. According to the hierarchical management standard of hospitals, hospitals are divided into 3 levels. Until October 2019, 2,671 tertiary hospitals accounted for 7.91%, 9,410 secondary hospitals accounting for 27.88%, and 11,011 primary hospitals accounting for 32.62% of all hospitals in China. Primary hospitals are primary health care institutions whose main function is to provide primary prevention directly to the population; they rarely admit and treat patients with septic shock. Therefore, primary hospitals were not included in the scope of this study. Secondary hospitals are technical centers of regional medical treatment and prevention and the main body of diagnosis and septic shock treatment. Tertiary hospitals provide transregional, provincial, and municipal medical and health services and are medical technology centers in China. The main function of tertiary hospitals is to provide specialized medical services to treat critical and difficult diseases. We conducted this survey to identify

Table 6 Differences of medical quality indicators between tertiary and secondary hospitals

Variables	Tertiary hospitals	Secondary hospitals	P
Doctor to patient ratio of ICU	0.64±0.35	0.66±0.38	0.27
Nurse to patient ratio of ICU	1.94±0.76	1.86±0.74	0.02
Proportion of ICU in total inpatient bed occupancy	0.020±0.031	0.017±0.023	0.02
Proportion of APACHE II score ≥ 15 in all ICU patients	0.47±0.32	0.48±0.32	0.73

Proportion of ICU in total inpatient bed occupancy = (days of ICU bed occupancy by patients)/(days of hospital bed occupancy by patients at the same periods); proportion of APACHE II score ≥ 15 in all ICU patients (%) = (No. of patients with APACHE II score ≥ 15 during the first 24 h in ICU)/(patients admitted ICU at the same periods).

$C_{\text{ssc-1h}}$ differences in the management of septic shock between secondary hospitals and tertiary hospitals. In our study, $C_{\text{ssc-1h}}$ in tertiary hospitals was significantly higher than that in secondary hospitals. The reason for this could be that tertiary hospitals have greater technical and human resources. There were no statistical differences between tertiary hospitals and secondary hospitals in APACHE II score ≥ 15 and the proportion of ICU doctors/beds in our study. However, tertiary hospital ICUs have a higher proportion of nurses/beds and total inpatient bed occupancy than secondary hospital ICUs. These data indicate that there are no differences between tertiary hospitals and secondary hospitals in the degree of critical illness of patients admitted to the ICU and that the major difference between tertiary hospitals and secondary hospitals is not the doctor configuration, but in nurse configuration and total inpatient bed occupancy in the ICU. A higher proportion of total inpatient bed occupancy in the ICU often represents a stronger voice within China's hospital.

However, secondary hospitals are the main body of septic shock treatment. Most septic shock patients are treated in secondary hospitals. Therefore, there is an urgent need to improve $C_{\text{ssc-1h}}$ in secondary hospitals. According to the statistical results, there is still room for improvement in $C_{\text{ssc-1h}}$ in secondary hospitals, and quality control should be strengthened to improve $C_{\text{ssc-1h}}$ in secondary hospitals. Increasing the proportion of nurses/beds and total inpatient bed occupancy in ICUs of secondary hospitals may be an effective way to improve $C_{\text{ssc-1h}}$. In our survey on private hospitals, although most indicators of $C_{\text{ssc-1h}}$ in tertiary hospitals were higher than those in secondary hospitals, there were no statistical differences. This could be because the number of private hospitals included in this survey was too small, and further studies are needed to determine

whether there is a difference between $C_{\text{ssc-1h}}$ in tertiary hospitals and secondary hospitals in private hospitals.

According to ownership, hospitals in China are classified into public hospitals and private hospitals. Public hospitals are non-profit and receive financial subsidies from the state, so their medical prices are strictly limited. Private hospitals are generally profit-making hospitals under the government's supervision and are responsible for their profits and losses, with independent decisions made on medical prices. Since 1980, private hospitals began to appear in China's medical industry. The large-scale development of private hospitals in China was after 2001. Due to the shortage in public hospital funds, local governments focused their medical funds on private capital. In September 2001, China opened its medical market and encouraged the development of private medical institutions. The number of private hospitals began to increase continuously since then. In 2016, the number of private hospitals exceeded that of public hospitals for the first time. Until October 2019, the number of private hospitals in China had reached 21,838, while the number of public hospitals had been reduced to 11,914. With an increase in the number of private hospitals, the number of patients admitted with septic shock significantly increased. As technical force is still relatively weak, the general public, and even some medical professionals, generally believe that private hospitals are the weak link in treating septic shock. To identify $C_{\text{ssc-1h}}$ differences between public and private hospitals, we conducted this survey. It was surprising that there were no significant $C_{\text{ssc-1h}}$ differences between private hospitals and public hospitals in our study. From this perspective, private hospitals at the same level have the same septic shock diagnosis and treatment capabilities as public hospitals, and the development of private hospitals will not reduce $C_{\text{ssc-1h}}$.

Raised blood lactate concentrations are frequently viewed as evidence of tissue hypoxia and/or oxygen debt secondary to hypoperfusion (8,9). Serum lactate level is a sign of tissue hypoperfusion and an independent prognostic factor of septic shock (10). Studies have shown that lactate clearance $\geq 10\%$ within 6 hours of resuscitation may indicate a lower case fatality rate (11,12). Our previous clinical studies have shown that the ladder-oriented strategy of lactate scavenging can significantly reduce the mortality of shock patients (13-15), and we proposed to optimize the scavenging of lactate by respiratory quotient $[P(v-a)CO_2/C(a-v)O_2]$ (16,17). In public hospitals, the completion of measure lactate level and remeasure lactate level in tertiary hospitals was significantly higher than that in secondary hospitals. Both in tertiary and secondary hospitals, the completion of measure lactate level and remeasure lactate level between public hospitals and private hospitals were not statistically different. Stratification of measuring lactate level and remeasure lactate in tertiary hospitals was significantly higher than that in secondary hospitals. This phenomenon suggests that we should improve the completion of measure lactate level and remeasure lactate level in secondary hospitals.

Sterilization of cultures can occur within minutes of the first dose of an appropriate antimicrobial (16), so cultures must be obtained before antibiotic administration to optimize pathogens' identification and improve outcomes (17). Appropriate blood cultures include at least aerobic and anaerobic blood cultures. In public hospitals, the completion of obtaining blood cultures before administering antibiotics in tertiary hospitals was significantly higher than that in secondary hospitals. Both in tertiary and secondary hospitals, the completion of obtaining blood cultures before administering antibiotics between public hospitals and private hospitals was not statistically different. Stratification of completion of obtaining blood cultures before administering antibiotics in tertiary hospitals was significantly higher than that in secondary hospitals. This phenomenon suggests that we should improve the completion of obtaining blood cultures before administering antibiotics in secondary hospitals.

Empiric broad-spectrum therapy to cover all likely pathogens should be started immediately in septic shock (18). Empiric antimicrobial therapy should be narrowed once pathogen identification and sensitivities are established. The completion of empiric broad-spectrum therapy between public hospitals and private

hospitals, tertiary hospitals, and secondary hospitals was not statistically different. This could be because most hospitals do this well; all had a median of 100.

Early effective fluid resuscitation is crucial for septic shock. Initial fluid resuscitation should begin immediately upon recognizing a patient with hypotension and elevated lactate and completed within 3 hours of recognition. The completion of early effective fluid resuscitation between public hospitals and private hospitals, tertiary hospitals, and secondary hospitals was not statistically different. The reason for this could be that initiating the rapid administration of 30 mL/kg crystalloid for hypotension or lactate ≥ 4 mmol/L has been the usual practice in the early stages of resuscitation (19).

Urgent restoration of adequate perfusion pressure to the vital organs is a key part of resuscitation. This should not be delayed. If blood pressure is not restored after initial fluid resuscitation, then vasopressors should be commenced within the first hour to achieve a mean arterial pressure of ≥ 65 mmHg (20). In public hospitals, the completion of applying vasopressors in tertiary hospitals was significantly higher than that in secondary hospitals. Both in tertiary and secondary hospitals, the completion of applying vasopressors between public hospitals and private hospitals was not statistically different. Stratification of the completion of applying vasopressors in tertiary hospitals was significantly higher than that in secondary hospitals. This suggests that we should improve the completion of applying vasopressors in secondary hospitals.

The present study has some limitations. First, only 1 year of data was included in the study, and the effects of hospital level and ownership on $C_{\text{ssc-1h}}$ could not be analyzed continuously and dynamically. Second, compared with the proportion of private hospitals in terms of actual hospital composition, the number of private hospitals included in the study was relatively small, which may cause differences between survey results and real-life settings. It is necessary to conduct further studies using large samples of private hospitals.

Conclusions

$C_{\text{ssc-1h}}$ in tertiary hospitals was significantly higher than that in secondary hospitals. There is an urgent need to improve $C_{\text{ssc-1h}}$ in secondary hospitals. There were no statistical differences in the $C_{\text{ssc-1h}}$ in public hospitals and private hospitals; therefore, the increase in private hospitals will not

reduce $C_{\text{ssc-1h}}$.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The trial protocol was approved by the central institutional review board at Peking Union Medical College Hospital (No. S-K1297) and individual consent for this retrospective analysis was waived.

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