Effectiveness of an artificial intelligence clinical assistant decision support system to improve the incidence of hospital-associated venous thromboembolism: a prospective, randomised controlled study

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ABSTRACT

Background Thromboprophylaxis has been determined to be safe, effective and cost-effective for hospitalised patients at venous thromboembolism (VTE) risk. However, Chinese medical institutions have not yet fully used or improperly used thromboprophylaxis. The effectiveness of information technology applied to thromboprophylaxis in hospitalised patients has been proved in many retrospective studies, lacking of prospective research evidence.

Methods All hospitalised patients aged >18 years not discharged within 24 hours from 1 September 2020 to 31 May 2021 were prospectively enrolled. Patients were randomly assigned to the control (8890 patients) or intervention group (8895 patients). The control group implemented conventional VTE prevention programmes; the intervention group implemented an Artificial Intelligence Clinical Assistant Decision Support System (AI-CDSS) on the basis of conventional prevention. Intergroup demographics, disease status, hospital length of stay (LOS), VTE risk assessment and VTE prophylaxis were compared using the \( \chi^2 \) test, Fisher’s exact test, t-test or Wilcoxon rank-sum test. Univariate and multivariate logistic regressions were used to explore the risk factor of VTE.

Results The control and intervention groups had similar baseline characteristics. The mean age was 58.32±15.41 years, and mean LOS was 7.82±7.07 days. In total, 5027 (25.40%) and 2707 (13.67%) patients were assessed as having intermediate- to high VTE risk and high bleeding risk, respectively. The incidence of hospital- associated VTE (HA-VTE) was 0.38%, of which 86.84% had deep vein thrombosis. Compared with the control group, the incidence of HA-VTE decreased by 46.00%, mechanical prophylaxis rate increased by 24.00% and intensity of drug use increased by 9.72% in the intervention group. However, AI-CDSS use did not increase the number of clinical diagnostic tests, prophylaxis rate or appropriate prophylaxis rate.

Conclusions Thromboprophylaxis is inadequate in hospitalised patients with VTE risk. The role of AI-CDSS in VTE risk management is unknown and needs further in-depth study.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Venous thromboembolism (VTE), preventable and treatable but insufficiently prevented, is a serious health threat to hospitalised patients worldwide. In China, improving the VTE standard prevention rate has been included by the National Health Commission in the national medical quality and safety goals for 2021, 2022 and 2023. The Artificial Intelligence Clinical Assistant Decision Support System (AI-CDSS) has been applied to hospital- associated VTE prophylaxis information system construction. We developed a quality improvement plan for prospective clinical trials to validate the effectiveness of AI-CDSS.

WHAT THIS STUDY ADDS

⇒ We used AI-CDSS to automatically and accurately obtain large-scale randomised controlled study data in a short period of time with extremely low labour costs, improving the efficiency and effectiveness of research. The AI-CDSS was used for VTE prophylaxis of inpatients, which greatly reduced medical costs, and precise preventive measures could protect patients from VTE risks to the greatest extent.

INTRODUCTION

Venous thromboembolism (VTE), which includes deep vein thrombosis (DVT) and...
pulmonary embolism (PE), is a leading cause of unexpected death and preventable death in hospitalised patients. It is also an important direct cause of death for tumour and surgical inpatients, affecting nearly 10 million people annually worldwide. The global annual population incidences of PE and DVT are 39–115 per 100 000 people and 53–162 per 100 000 people, respectively. In China, the prevalence of VTE increased from 3.2 per 100 000 people in 2007 to 17.5 per 100 000 people in 2016. Approximately 60% of all VTE events occur as a result of a current or recent hospital admission, mainly for surgery (24%) or medical illnesses (22%). The incidence is increasing due to various factors, such as ageing population, major surgery, prolonged immobilisation, obesity, major trauma, caesarean deliveries, cancer and more advanced imaging techniques (CT scanning).

Many randomised controlled trials have proven that primary thromboprophylaxis of hospital-associated VTE (HA-VTE) is safe, effective and cost-effective in reducing the incidence of DVT and PE, which has allowed the medical community to reach a consensus for the use of thromboprophylaxis. However, Chinese medical institutions have not yet fully used or have improperly used thrombosis prevention measures when compared at the international level. A multicentre cross-sectional study in a tertiary hospital in China on the results of VTE risk showed that only 9% of 13 609 hospitalised patients received VTE prophylaxis as per the American College of Chest Physicians (ACCP) guidelines (medical 6.0%, surgical 11.8%), which is significantly lower than that of the multicentre Epidemiologic International Day for the evaluation of Patients at Risk for Venous Thromboembolism in the Acute Hospital Care Setting study (medical 43%, surgery 55%).

In an effort to reduce preventable mortality and morbidity in hospital settings, the National Health Commission has regarded VTE prophylaxis as an important health policy and one of the national medical quality and safety improvement goals of 2021, 2022 and 2023. Various types of system-wide intervention measures have been proposed by various medical institutions across the country to improve thromboprophylaxis in hospitalised patients, such as publicity and education, issuance of guides and manuals, and training and forums. We previously showed that alarms, especially computer alarms linked to multiple interventions, are more effective than other preventive solutions. However, these results were based on observational retrospective studies (with low-to-moderate-certainty evidence); therefore, a higher level of evidence from randomised controlled studies is needed.

METHODS

Study design

This was a randomised controlled single-centre prospective study (ChiCTR2000035452). The study protocol was approved by the hospital ethics committee (No. 164). Informed consent was obtained from all patients in the groups. All doctors received the hospital’s VTE prevention and treatment knowledge training and obtained a VTE prevention and treatment manual.

Artificial Intelligence Clinical Assistant Decision Support System (AI-CDSS) is a big data governance system based on natural language processing, knowledge mapping, machine learning and other technologies. In clinical applications, it can achieve the structuring, standardisation and normalisation of various clinical data. The research hospital uses the data processing function of AI-CDSS to install it in the hospital information system, connect electronic medical records, laboratories and imaging detection systems, and automatically identify and extract patient VTE-related medical record information such as diagnosis, examination, treatment and medical advice. The VTE risk assessment scale (Caprini for surgical patients, Padua for non-surgical patients and Wells for PE) and the bleeding risk assessment scale were also embedded in the AI-CDSS system, which automatically collected information on VTE risk scores, bleeding risk scores and Wells scores for hospitalised patients every 6 hours or whenever a doctor entered the electronic medical record system. When the assessment results showed the patient was at increased risk, the AI-CDSS system would give doctors corresponding preventive pop-up reminders, which are determined based on the ACCP guidelines (9th edition) and discussions with hospital experts. The doctors would administer appropriate prophylaxis for patients based on the patient’s condition and pop-up window reminder content. Specific auxiliary decision support was as follows: AI-CDSS recommended intravenous B-ultrasound for VTE high-risk and Wells high-risk patients. D-dimer test (DDI) was recommended for VTE high-risk and Wells low-risk patients. Mechanical prevention or/and drug prevention was recommended for VTE intermediate risk. Preventive anticoagulation or/and mechanical prevention was recommended for VTE high-risk and bleeding low-risk patients. A warning would be given for VTE intermediate-high-risk and bleeding high-risk if a doctor prescribed anticoagulant drugs. AI-CDSS reminded all patients who were prescribed mechanical prophylaxis to undergo the lower extremity ultrasound screening within 72 hours. If the ultrasound examination found DVT formation (including suspicious) and CT pulmonary angiography found PE (including suspicious), AI-CDSS reminded the doctor to pay attention via corporate WeChat.

Hospitalised patients who met the inclusion criteria were randomly assigned to the control or intervention groups. The control group underwent routine prophylactic interventions (eg, a unified VTE prevention knowledge training and publicity education manual for the entire hospital, and occasional supervision by the medical department) according to the hospital’s existing practice, but without computer alerts, the AI-CDSS used in the intervention group was linked to the recommended thromboprophylaxis intervention. Demographics, disease status, clinical diagnostic test results, VTE prophylaxis...
and HAVTE events were statistically analysed to assess the effectiveness of the AI-CDSS.

Randomisation and masking
The study was stratified according to clinical departments. Each department used computer excel software to generate random serial numbers according to the precalculated sample size. The first half of the random serial numbers was assigned to the intervention group and the other half to the control group. The study design began at 06:00 the day after the patient was admitted to the hospital. The AI-CDSS automatically runs the inclusion and exclusion rules, assigns random serial numbers to selected inpatients in the order of admission and includes patients into corresponding groups according to the random serial number grouping. The patient enrolment process was completely computer-controlled, and the clinical staff, investigators and patients involved in this study were strictly masked for enrolment during the trial.

The random serial number and grouping table files are copied by the database administrator in three copies, stored in three blank data discs and then put into three sealed envelopes, respectively, sealed with glue and stamped with a special seal. Principle investigator, database administrator and Sponsor each keep a data disc in the safe.

Patients and procedures
The sample size calculation was based on an estimation of the prevalence (0.549%) of HA-VTE at our hospital in 2019. If the incidence of VTE in the experimental group decreased by 50%, then 120% of the calculated sample size was used as the actual sample size, with a randomised inclusion of 10248 patients in each of the experimental and control groups.

Estimation formula of sample size:

\[ N = \frac{(Z_{\alpha/2} + Z_{\beta})^2}{(p_1 - p_2)^2} \times \left[p_1(1 - p_1) + p_2(1 - p_2)\right], \]

\( \alpha = 0.05, \ \beta = 0.8 \)

All hospitalised patients aged >18 years who were not discharged within 24 hours of hospital admission from 1 September 2020 to 31 May 2021 from high-risk departments were prospectively screened. Patients were assessed from 24 departments with a VTE incidence rate >0.1% in 2019, such as the trauma surgery, respiratory, emergency intensive care unit, medical emergency, neurosurgery and thoracic surgery departments. However, hospitalised patients would not be included if they were diagnosed as having DVT or PE using the International Classification of Diseases 10th Revision (ICD-10) at the time of admission, if they had taken part in a similar clinical trial, if the expected hospital stay was <24 hours or if they received full anticoagulant therapy (figure 1).

Case identification
VTE risk was evaluated using the Padua prediction score or Caprini risk assessment model, and Wells score for preclinical probabilistic assessment of DVT risk. Dynamic evaluations were further conducted if the patient’s condition changed depending on VTE and bleeding risk. To identify cases, discharge diagnoses were collected using the ICD-10 coding system at each site. PE was diagnosed using ICD-10 codes I26.0 or I26.9; DVT was identified using ICD-10 codes I80.1, I80.2, I80.3, I80.8, I80.9, I82.8, I82.9, O22.3, O22.9 or O87.1. A combination of PE with or without DVT codes and DVT codes alone was then used to determine VTE. The accuracy of ICD-10 in detecting symptomatic VTE has been previously validated with high specificity and acceptable sensitivity.

Statistical analysis
Continuous variables are presented as the number of observations, mean and SD; t-test was used according to whether they conform to normal distribution. Categorical variables are presented as the number (%) of baseline characteristics and evaluated using the \( \chi^2 \) test or Fisher’s exact probability method. Missing values and outliers were replaced with the means. Statistical significance was set at two-tailed \( p \) values <0.05. All statistical analyses were performed using R V.4.0.2.

RESULTS
Baseline characteristics of patients
The 19785 eligible inpatients (mean age, 58.32±15.41 years; 53.58% men) were included in the full analysis set. The effective rates of data in the control group and the intervention group were 96.50% and 96.55%, respectively. The two groups had similar baseline characteristics (table 1). The control group (n=9890) comprised 4663 (47.15%) female participants the distributions of age and body mass index (BMI) were 58.38±15.43 years and 23.62±3.68 kg/m², respectively; the intervention
group (n=9895) comprised 4521 (45.69%) female participants which the distributions of age and BMI were 58.26±15.39 years and a BMI of 23.71±3.68 kg/m², respectively. The distribution of LOS was 7.82±7.07 days for the overall population, 7.81±6.98 days for the control group and 7.82±7.15 days for the intervention group. The main reasons for hospitalisation were surgery (37.83%), all types of cancer requiring chemotherapy, surgery, palliative care, etc (29.56%), hypertension (28.57%), diabetes (12.84%) or renal failure (9.73%) (table 1).

VTE and bleeding risk stratification and VTE risk factors
A total of 5027 (25.40%) and 2707 (13.67%) patients were assessed as having intermediate-to-high VTE risk and high bleeding risk, respectively, and a total of 517 (2.61%) patients had a high risk of VTE and bleeding.

Of these hospitalised patients, 2461 (24.88%) and 1357 (13.72%) patients in the control group and 2566 (25.94%) and 1350 (13.65%) patients in the intervention group were assessed as having intermediate-to-high VTE risk and high bleeding risk, respectively (table 2).

VTE risk factors obtained by Poisson regression analysis to control for potential confounders were age ≥75 years (OR: 2.34, 95% CI (1.34 to 3.98)), LOS (OR: 24.72, 95% CI (8.72 to 90.33)), allergic history (OR: 2.33, 95% CI (1.20 to 4.21)) and heart failure (OR: 2.51, 95% CI (1.07 to 5.52)).

Clinical diagnostic tests
According to the study design, the diagnosis of VTE requires relevant laboratory tests. Inpatients with a high risk of VTE and high Wells score should undergo

### Table 1 Baseline and demographic characteristics of hospitalised patients

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control group (n=9890)</th>
<th>Intervention group (n=9895)</th>
<th>Total (n=19785)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>4663 (47.15)</td>
<td>4521 (45.69)</td>
<td>10084 (53.58)</td>
</tr>
<tr>
<td>Age, n (mean±SD)</td>
<td>1130 (58.38±15.43)</td>
<td>1138 (58.26±15.39)</td>
<td>2268 (58.32±15.41)</td>
</tr>
<tr>
<td>BMI (kg/m²), n (mean±SD)</td>
<td>3242 (23.62±3.68)</td>
<td>3386 (23.71±3.68)</td>
<td>6628 (23.67±3.68)</td>
</tr>
<tr>
<td>Weight (kg), Median (Mean±SD)</td>
<td>64 (65.1±12.6)</td>
<td>65 (65.5±12.7)</td>
<td>129 (65.30±12.65)</td>
</tr>
<tr>
<td>LOS (d), (Mean±SD)</td>
<td>7.81±6.98</td>
<td>7.82±7.15</td>
<td>7.82±7.07</td>
</tr>
<tr>
<td>Diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery history, No. (%)</td>
<td>3699 (37.40)</td>
<td>3785 (38.25)</td>
<td>7484 (37.83)</td>
</tr>
<tr>
<td>Allergy history, No. (%)</td>
<td>845 (8.54)</td>
<td>868 (8.77)</td>
<td>1713 (8.66)</td>
</tr>
<tr>
<td>Cancer history, No. (%)</td>
<td>2925 (29.58)</td>
<td>2924 (29.55)</td>
<td>5849 (29.56)</td>
</tr>
<tr>
<td>Fracture history, No. (%)</td>
<td>293 (2.96)</td>
<td>316 (3.19)</td>
<td>609 (3.08)</td>
</tr>
<tr>
<td>Heart failure history, No. (%)</td>
<td>2878 (29.1)</td>
<td>2775 (28.04)</td>
<td>5653 (28.57)</td>
</tr>
<tr>
<td>Acute myocardial infarction history, No. (%)</td>
<td>34 (0.34)</td>
<td>30 (0.30)</td>
<td>64 (0.32)</td>
</tr>
<tr>
<td>Diabetes history, No. (%)</td>
<td>1262 (12.76)</td>
<td>1279 (12.93)</td>
<td>2541 (12.84)</td>
</tr>
<tr>
<td>Heart failure history, No. (%)</td>
<td>607 (6.14)</td>
<td>612 (6.18)</td>
<td>1219 (3.16)</td>
</tr>
<tr>
<td>Renal failure history, No. (%)</td>
<td>977 (9.88)</td>
<td>948 (9.58)</td>
<td>1925 (9.73)</td>
</tr>
<tr>
<td>Chronic lung disease history, No. (%)</td>
<td>269 (2.72)</td>
<td>276 (2.79)</td>
<td>545 (2.75)</td>
</tr>
</tbody>
</table>

Weight: four missing values, mean interpolation.
BMI, body mass index; LOS, length of stay; SD, standard deviation; Weight, 4 missing values, mean interpolation.

### Table 2 VTE and bleeding risk stratification within 24 hours of admission in hospitalised patients

<table>
<thead>
<tr>
<th>VTE and bleeding risk stratification</th>
<th>Control group (n=9890)</th>
<th>Intervention group (n=9895)</th>
<th>Total (n=19785)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low VTE and low bleeding risk</td>
<td>6723 (67.98)</td>
<td>6663 (67.34)</td>
<td>13386 (67.66)</td>
</tr>
<tr>
<td>Low VTE and high bleeding risk</td>
<td>706 (7.14)</td>
<td>666 (6.73)</td>
<td>1372 (6.93)</td>
</tr>
<tr>
<td>Intermediate VTE and low bleeding risk</td>
<td>812 (8.21)</td>
<td>806 (8.15)</td>
<td>1618 (8.18)</td>
</tr>
<tr>
<td>Intermediate VTE and high bleeding risk</td>
<td>383 (3.87)</td>
<td>435 (4.40)</td>
<td>818 (4.13)</td>
</tr>
<tr>
<td>High VTE and low bleeding risk</td>
<td>998 (10.09)</td>
<td>1076 (10.87)</td>
<td>2074 (10.48)</td>
</tr>
<tr>
<td>High VTE and high bleeding risk</td>
<td>268 (2.71)</td>
<td>249 (2.52)</td>
<td>517 (2.61)</td>
</tr>
</tbody>
</table>

VTE, venous thromboembolism.
intravenous B-ultrasound examination, and inpatients with a high risk of VTE and low Wells score should undergo DDI examination. There was no statistical difference between the control and intervention groups when comparing ultrasound findings of the lower extremity veins, venography and DDI examination, which indicated that AI-CDSS did not increase auxiliary medical examination.

**Administration of VTE prophylaxis**

Appropriate prophylaxis was determined based on the VTE and bleeding risks. Pharmaceutical, mechanical and joint interventions were adapted accordingly; 19,875 patients of whom 5027 were intermediate or high risk were included in the final analysis. Of these, 772 (3.90%) patients with intermediate/high VTE risk received mechanical or pharmacological prophylaxis, including 252 (3.45%) patients in the control group and 256 (3.44%) patients in the intervention group. There were no significant differences between the control and intervention groups for any prophylaxis administration, appropriate prophylaxis administration or low risk over prophylaxis administration (table 3).

**Distribution of VTE events during hospitalisation**

VTE events during hospitalisation occurred in 76 inpatients, with an overall incidence of 3.84 per 1000 (76 episodes in 19,785 inpatients) patients. The positive impact observed with the AI-CDSS is supported over time. VTE events occurred less frequently in the intervention group (2.7 per 1000 patients, 27 episodes in 9895 inpatients) than in the control group (5.0 per 1000 patients, 49 episodes in 9890 inpatients), or a relative reduction of 46.00% (OR: 0.55, 95% CI (0.34 to 0.83)). The incidence of DVT (0.33%) was much higher than that of PE (0.08%) in the control group (DVT, 0.44%; PE, 0.10%) and the intervention group (DVT, 0.22%; PE, 0.06%). A fatal PE event occurred in the control group (table 4).

### Table 3 VTE prophylaxis of hospitalised patients within 24 hours of admission in the control and intervention groups

<table>
<thead>
<tr>
<th>Measure</th>
<th>Control group (n=9890)</th>
<th>Intervention group (n=9895)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>L-VTE-B (n=6723)</td>
<td>L-VTE-B (n=6663)</td>
</tr>
<tr>
<td>Pharmacologic prophylaxis, n (%)</td>
<td>204 (3.03)</td>
<td>195 (2.93)</td>
</tr>
<tr>
<td>Mechanical prophylaxis, n (%)</td>
<td>33 (3.68)</td>
<td>28 (4.20)</td>
</tr>
<tr>
<td>Pharmacologic and mechanical prophylaxis, n (%)</td>
<td>67 (3.70)</td>
<td>2 (0.30)</td>
</tr>
</tbody>
</table>

### Table 4 Distribution of VTE events in hospitalised patients

<table>
<thead>
<tr>
<th>VTE characteristic</th>
<th>Overall (n=19785)</th>
<th>Control group (n=9890)</th>
<th>Intervention group (n=9895)</th>
<th>P value</th>
<th>OR (95%CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>VTE, No. (%)</td>
<td>76 (0.38)</td>
<td>49 (0.50)</td>
<td>27 (0.27)</td>
<td>0.01</td>
<td>0.55 (0.34 to 0.88)</td>
</tr>
<tr>
<td>DVT, No. (%)</td>
<td>61 (0.33)</td>
<td>40 (0.44)</td>
<td>21 (0.21)</td>
<td>0.02</td>
<td>0.52 (0.31 to 0.89)</td>
</tr>
<tr>
<td>PE, No. (%)</td>
<td>10 (0.05)</td>
<td>5 (0.05)</td>
<td>5 (0.05)</td>
<td>1.00</td>
<td>0.99 (0.29 to 3.45)</td>
</tr>
<tr>
<td>DVT and PE, No. (%)</td>
<td>5 (0.003)</td>
<td>4 (0.04)</td>
<td>1 (0.01)</td>
<td>0.18</td>
<td>0.25 (0.03 to 2.24)</td>
</tr>
</tbody>
</table>

DVT, deep vein thrombosis; OR, odds ratio; PE, pulmonary embolism; VTE, venous thromboembolism.
DISCUSSION

To our knowledge, this is the first prospective clinical trial in China to evaluate the implementation of recommended HA-VTE thromboprophylaxis through the use of AI-CDSS intervention. We obtained large-scale randomised controlled study data in a short period of time with extremely low labour costs, which provided real evidence for medical quality and safety improvement goals and HA-VTE prophylaxis information construction. The AI-CDSS facilitates the identification of hospitalised patients at an increased risk of VTE and bleeding in the absence of prophylaxis. This study showed that the incidence of HA-VTE was 0.38%, which was slightly higher than that in Chinese hospitalised patients,24 of which 86.84% were patients with DVT. Compared with the control group, the incidence of HA-VTE was reduced by 46.00%, events related to HA-VTE decreased, which may be explained partly by the increased use of prophylaxis, the mechanical prophylaxis rate increased by 24.00% and the intensity of drug use increased by 9.72% in the intervention group. Thus, the large increase in mechanical prophylaxis offsets the increase in DVT occurrence. Whether this is closely related to the application of AI-CDSS in VTE risk management needs further study in the future. It is undeniable that the application of AI-CDSS automatic warning will meet the growing demand of hospitals for health information technology, which is gradually being popularised in Chinese medical institutions.

Although early VTE prophylaxis is recommended, a survey of nearly 14000 hospitalised patients in China showed that only 14.27% of hospitalised patients with VTE risk have received thromboprophylaxis intervention, and only 10.30% of patients have received appropriate prevention,24 while an international multicentre survey showed that 51.80% of hospitalised patients were at risk of VTE, of whom 50.20% received appropriate prophylaxis,25 which proves that a large number of hospitalised patients in China have insufficient demand for thromboprophylaxis and treatment, and lack protection. In our experimental study, only 3.90% of hospitalised patients received any preventive measures and 3.18% of the intermediate-to-high VTE risk patients received appropriate preventive measures. Although these data were only thromboprophylaxis data obtained within 24 hours of admission and cannot represent the overall prophylaxis status, however, when compared with the 25.40% and 13.67% of hospitalised patients with intermediate-to-high VTE risk and high bleeding risk, respectively, within 24 hours of admission, there was no doubt that hospitalised patients with VTE risk received any prophylaxis, and appropriate prophylaxis administration was seriously insufficient. Another important finding of our study was that among inpatients classified as having received inappropriate thromboprophylaxis, most (1.93%) received thromboprophylaxis when they were not supposed to. Meanwhile, 3.44% of patients with low VTE risk were overtreated. These findings suggest that thromboprophylaxis is inadequate in hospitalised patients with VTE risk, especially appropriate thromboprophylaxis, and that low-risk patients are at risk of over prophylaxis. Appropriate thromboprophylaxis is a life-saving and cost-effective strategy,26 which requires consideration of availability, cost, patient preference, compliance, comorbidities and other factors.27 Low-risk over prophylaxis not only increases additional cost but also exposes patients to unnecessary bleeding risk. Therefore, reasonable measures should be taken to improve appropriate thromboprophylaxis in patients with intermediate-to-high VTE risk and reduce over prophylaxis in patients with a low VTE risk.

In our study protocol, VTE diagnosis required a sequential work-up that combined assessment of clinical pretest probability for VTE using a clinical score (eg, Wells, Padua or Caprini), DDI testing and imaging.7 Under the premise that the risk of VTE in the control and intervention groups was relatively balanced, the use of AI-CDSS did not increase the clinical diagnostic tests. In addition, the AI-CDSS will alert clinicians to provide patients with appropriate prophylaxis measures in a timely manner, according to changes in patients’ VTE and bleeding risk.26 However, prophylaxis and appropriate prophylaxis rates have not been effectively improved. The reason may be that clinical data are scattered in various system databases. Based on the heterogeneity of different data sources, AI-CDSS cannot prepare to capture all clinically important data related to VTE, such as PE and DVT severity. Therefore, it is necessary to adjust and improve the design of AI-CDSS to meet clinical needs. Another point is that the management of VTE prevention depends more on the professional knowledge, diagnosis and treatment behaviour of doctors. However, AI-CDSS has not been online for a long time, and the compliance of clinicians is not high. Many doctors still do not know the importance of VTE risk assessment and thromboprophylaxis.29 Therefore, we suggest implementing evidence-based education programmes,30 strengthening health education for clinicians and improving thromboprophylaxis awareness and appropriate thromboprophylaxis rate.

According to the Asian VTE guidelines, VTE incidence is increasing because of a number of factors: ageing population, higher rates of major complex surgeries, higher rates of caesarean deliveries, increase in obesity and increased incidence of cancer coupled with low rates of thromboprophylaxis.14 There is also a convincing study demonstrating that VTE risk factors include increasing age, prolonged immobility, malignancy, major surgery, multiple traumas, previous VTE and chronic heart failure.14 Similar results were obtained in our study, which showed including age ≥ 75 years, LOS, history of allergies, hypertension, acute myocardial infarction, heart failure and renal failure as risk factors. This suggests that VTE is a multi-cause disease that can occur in patients from any department or with any disease. VTE-standardised prophylaxis requires multidisciplinary collaboration between clinics, management, medical technology, nursing and
pharmacies. It is necessary to establish a multidisciplinary collaborative prevention and control system at the hospital management level to truly intervene based on the risk factors. Another interesting result was found when we used regression analysis to compare the incidence of VTE in hospitalised patients in the control and intervention groups by demographic and sociological characteristics: the incidence of VTE events in the intervention group was lower in women, those aged <75 years, those with BMI <30 kg/m², and those with no allergic or surgical history, and those with no cancer, no fracture, hypertension, no acute myocardial infarction, no diabetes, heart failure, no renal failure and no chronic lung disease. In other words, the use of AI-CDSS had a better intervention effect in the patient population with these characteristics, which may be related to patient characteristics and disease severity. The AI-CDSS was effective in patients with a wide spectrum of major risk factors for VTE. Further reasons will be explored in upcoming experimental studies.

Since clinical data are scattered in various system databases, the AI-CDSS cannot capture all clinically important data related to VTE, such as PE and DVT severity. Moreover, the information system of each hospital is very different, and the design of AI-CDSS needs to be adjusted and improved. This study analysed the risk announcement, clinical diagnosis and preventive management of inpatients not discharged within 24 hours of hospital admission. It did not include data on discharge and post-hospital follow-up and could not represent the overall situation of VTE in all inpatients. In addition, this was a single-centre study, and the results cannot be generalised.

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