



## Regular Article

## Venous thromboembolism risk assessment and thromboprophylaxis among hospitalized acute medical patients in China – the RAMP study

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## ABSTRACT

**Background:** In developed countries, hospitalized patients with acute medical conditions are at significant risk for venous thromboembolism (VTE). Little is known about VTE risk and prophylaxis practices in China. **Objective:** To determine the VTE risk and the frequency of recommended VTE prophylaxis in hospitalized Chinese patients with acute medical conditions.

**Methods:** Multi-center, cross-sectional, observational study. Eligibility criteria:  $\geq 30$  years, admitted to an intensive care unit (ICU)/coronary care unit (CCU) for acute medical illness, had  $\geq 1$  VTE risk factor/1 disease that predisposes to VTE, and provided informed consent. We used 2004 American College of Chest Physicians (ACCP) evidence-based consensus guidelines to assess VTE risk and the frequency of recommended VTE prophylaxis.

**Results:** 1247 patients from 19 hospitals in 11 cities across 11 provinces of China were enrolled from July 2007 to June 2008. 57.3% patients had  $>2$  VTE risk factors. Only 20.2% received ACCP-recommended VTE prophylaxis (CCU patients: 22.7%, ICU patients: 16.9%,  $p = 0.0117$ ).

**Limitations:** Excluding some patients with VTE risk factors did not allow assessment of the prevalence of VTE risk in the acute hospital-care setting. We could not determine whether the duration of prophylaxis complied with the ACCP recommendations. Our results may not be representative of hospitals in small cities/rural areas in China.

**Conclusions:** The prevalence of VTE risk factors in Chinese patients was similar to that in developed countries; however, only a small proportion of eligible patients received the recommended VTE prophylaxis. Our findings highlight the need for dissemination and implementation of appropriate VTE prophylaxis guidelines in China.

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## Introduction

Venous thromboembolism (VTE), including pulmonary embolism (PE) and proximal deep-vein thrombosis (DVT), is a serious complication among hospitalized patients and a major cause of in-hospital mortality. Studies from Western countries have reported that PE is associated with up to 10% of deaths among hospitalized patients [1–3]. Every year, more than 25,000 hospitalized patients in England die from VTE [4]. A study from Hong Kong showed that the hospital mortality rates attributable to DVT and PE were 7.3%

and 23.8%, respectively [5]. Previous studies have showed that in the absence of adequate thromboprophylaxis, approximately 10%–40% of general medical patients are at risk for developing DVT or PE [6,7]. In acutely ill medical patients, this percentage is higher [8].

Emerging evidence indicates that VTE can be prevented. In the 8th edition of Clinical Practice Guidelines for VTE prevention, the American College of Chest Physicians (ACCP) recommend that the risk of VTE should be assessed in all patients on admission to the intensive care unit (ICU), and that thromboprophylaxis should be administered to patients who are at risk for VTE (Grade 1A) [9]. However, despite this clear ACCP guideline, adherence to the above recommendation is poor. Recently, the ENDORSE study [10], which included 358 hospitals from 32 countries in 6 continents, indicated that only 39.5% of eligible at-risk medical patients received ACCP-recommended VTE prophylaxis (ranging from 2% to 84% among different countries). Physician awareness, availability of the guidelines, educational factors, reimbursement, and national health-care resources are responsible for the large variability observed in the administration of VTE prophylaxis.

**Abbreviations:** ACCP, American College of Chest Physicians; ANOVA, analysis of variance; CRF, case report forms; CCU, coronary care unit; DVT, deep-vein thrombosis; ICU, intensive care unit; IQR, interquartile range; LMWH, low molecular weight heparin; NYHA, New York Heart Association; PE, pulmonary embolism; SD, standard deviation; UFH, unfractionated heparin; RAMP, VTE Risk Assessment and Thromboprophylaxis among Hospitalized Acute Medical Patients in China; VTE, venous thromboembolism.

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In mainland China, the awareness of the risk of VTE in medical patients and information about the associated prophylactic practices are limited. The RAMP study was designed (a) to identify the risk factors for VTE in hospitalized acutely ill medical patients in representative hospitals in China and (b) to determine the frequency of VTE prophylaxis in eligible at-risk patients, as defined by the 2004 ACCP evidence-based consensus guidelines [11]. We aimed to develop a formal strategy that addresses the prevention of VTE in China on the basis of the results of this study.

## Methods

### Patient screening and enrollment

This study is a national cross-sectional survey. Using a 2-stage sampling process, 11 representative cities in 11 provinces of China were selected during the first stage. In the second stage, a random proportional sample from authoritative lists of general hospitals (with ICUs and/or coronary care units [CCUs]) within the selected cities was created, and the hospitals in this sample were invited to participate in the study. Trained physicians in each participating hospital systematically screened all patients hospitalized in ICUs and/or CCUs between July 2007 and June 2008 and then enrolled the first 10–100 (depending on the number of beds in the ICUs/CCUs) eligible patients according to predefined inclusion and exclusion criteria (given below). Patient management was determined by the physicians in charge. These physicians were not involved in the RAMP study since the study aimed to reflect the actual approach to VTE prophylaxis used in China.

The inclusion criteria for the RAMP study were as follows: (i) age  $\geq 30$  years; (ii) admission to an ICU or a CCU for an acute medical illness; (iii) presence of at least 1 risk factor for VTE or 1 disease that predisposes to VTE, as defined by Cohen et al [12]; and (iv) provision of informed consent.

The patient exclusion criteria were as follows: (i) major surgery within 3 months prior to hospital admission, (ii) ongoing anticoagulant treatment for medical reasons (e.g., acute myocardial infarction), (iii) presence of predefined potential risk factors for bleeding (current gastrointestinal ulcer, bleeding disorder, hepatic failure, and hemorrhagic stroke), (iv) any medical condition associated with a predicted survival of less than 14 days, and (v) hospitalization in the ICU/CCU for less than 24 hours.

### Identification of risk factors for VTE

Assessment of VTE risk and the benefits of thromboprophylaxis were based on the procedures recommended by Cohen et al [12]. In brief, medical diseases or conditions associated with a high risk of VTE include (i) evidence-based illnesses/conditions (i.e., acute heart failure, New York Heart Association (NYHA) class III or IV; active cancer requiring therapy; acute infectious diseases; respiratory diseases; rheumatic disease; ischemic stroke; and paraplegia), (ii) consensus-based illnesses/conditions (i.e., inflammatory disorder with immobility and inflammatory bowel disease), (iii) evidence-based risks (i.e., history of VTE, history of malignancy, and age  $> 75$  years), and (iv) consensus-based risks (i.e., prolonged immobility, age  $> 60$  years, varicose veins, obesity, hormone therapy, pregnancy/postpartum state, nephrotic syndrome, dehydration, thrombophilia, and thrombocytosis).

### Data collection

The study was performed and coordinated under the guidance of a scientific advisory board. Data quality was monitored by the study coordinators throughout the study.

Initially, investigators evaluated every patient admitted in an ICU or a CCU during the study period in order to identify eligible patients; data from the eligible patients were obtained from medical records as well as from face-to-face interviews. All data were recorded in standardized case report forms (CRFs), which were completed before hospital discharge. Validated CRFs were sent to an independent data-coordinating center (Department of Epidemiology and Biostatistics, Zhongshan Hospital, Fudan University, Shanghai, China). We queried patients whose CRFs had missing pages, missing fields, inconsistent data, etc.

The recorded information included the following: demographic characteristics of the patients; diagnosis on admission; patients' risk factors for VTE (which were defined by Cohen et al [12] and were in accordance with the 2004 ACCP guidelines); and type of prophylaxis used (i.e., low-molecular-weight heparin [LMWH], unfractionated heparin [UFH], warfarin, aspirin, and intermittent pneumatic compression).

### Data analysis

Categorical data were expressed as absolute values and in terms of the percentage of the population. Quantitative data were expressed in terms of the mean (standard deviation [SD]), except for the data that did not show a normal distribution, which were expressed in terms of the median (interquartile range [IQR]). Statistical analysis was performed using Pearson  $\chi^2$  test to compare proportions and analysis of variance (ANOVA) to compare means. A 5% level of significance was accepted for all statistical tests. Data were analyzed with SAS version 8 statistical software package (SAS Institute, Inc., Cary, North Carolina, USA).

### Role of funding source

Sanofi-aventis was responsible for funding, study design, and monitoring. Principle investigator and his research team were responsible for data management and decision of submission.

## Results

### Characteristics of patients at risk for VTE

Between July 2007 and June 2008, a total of 1247 eligible at-risk patients were enrolled in the study from 19 hospitals in 11 cities (Beijing, Shanghai, Chongqing, Guanzhou, Nanjing, Wuhan, Hangzhou, Chendu, Qingdao, Shengyan, and Urumqi). Two cities had three active sites each, and four cities had two active sites each. Of the 19 participating hospitals, 16 had both ICUs and CCUs; 3 had only ICUs.

The demographics of the enrolled patients are summarized in Table 1. Of 1247 patients enrolled, 543 (44%) were hospitalized in ICUs, and 704 (56%), in CCUs. No statistical differences were observed

**Table 1**

Characteristics of the entire study population and of patients stratified by their medical care ward.

Patient Characteristics	ICU (N = 543)	CCU (N = 704)	Total (N = 1247)
Men, n (%)	367 (67.6)	399 (56.7)	766 (61.4)
Age (y), mean (SD)	68.8 (13.6)	69.0 (11.9)	69.0 (12.7)
Body mass index (kg/m <sup>2</sup> ), mean (SD)	22.7 (3.85)	23.3 (3.66)	23.0 (3.76)
Duration of hospitalization prior to survey commencement (d), median (IQR)	12 (6–21)	10 (5–16)	10 (6–18)

ICU: intensive care unit, CCU: coronary care unit, SD: standard deviation, IQR: interquartile range.

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