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## Left lower limb may be a forbidden region for indwelling needle during operation



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#### ABSTRACT

*Introduction:* Information about the incidence and risk factors of venous thromboembolism (VTE) after thyroid operation is limited. This study aimed to analyze the incidence and risk factors of postoperative VTE in patients who had undergone thyroid surgery.

*Materials and methods:* A prospective, multi-center cohort study was performed from June 2013 to June 2015 in 3 hospitals throughout South Central China. We analyzed 5029 patients who had undergone thyroid operation and received no VTE prophylaxis postoperatively. For the diagnosis of deep vein thrombosis (DVT), bilateral whole-leg ultrasound was conducted in patients with a high pretest probability of DVT. Lung ventilation/perfusion scintigraphy, pulmonary angiography, or helical computed tomography was implemented in patients suspected to have pulmonary embolism (PE).

*Results:* DVT was diagnosed in 18 patients (0.36%). No patient was diagnosed with PE. Binomial logistic regression analysis revealed that age and left lower limb intraoperative venous access (IVA) were significant risk factors for DVT. The incidence of DVT increased as the number of risk factors increased.

*Conclusions*: VTE is uncommon in patients who have undergone thyroid surgery. The left lower limb was not an appropriate insertion site IVA. Pharmacologic thromboprophylaxis was not mandatory, particularly in those patients without risk factors.

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#### 1. Introduction

Venous thromboembolism (VTE), including deep venous thrombosis (DVT) and pulmonary embolism (PE), is a common cause of preventable death among patients who have undergone surgery [1]. About onethird of VTE-related deaths per year in the USA occur after surgery [2]. The incidence of VTE is reported to be lower in Asian countries than that in Western countries [3,4]. However, recent studies indicate the incidence of VTE among Asians is increasing rapidly [5,6]. VTE is becoming an increasingly crucial public health problem in Asia. To our knowledge, the precise incidence and risk factors of VTE among patients who have undergone thyroid surgery in China have not been fully studied using

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prospective epidemiological studies. Thus, we aimed to investigate the rate and risk factors of VTE after thyroid surgery.

#### 2. Materials and methods

This is a prospective, multi-center cohort study of consecutive patients who had undergone thyroid surgery from June 2013 to June 2015 in 3 hospitals throughout south Central China.

#### 2.1. Patients

Consecutive patients aged  $\geq$  18 years who had undergone thyroid surgery were recruited from 3 hospitals in South Central China. The thyroid surgery included total thyroidectomy, residual thyroidectomy, lymph nodes dissection (thyroid surgery plus any compartment lymph nodes dissection), lobectomy and partial thyroidectomy. Exclusion criteria were pregnancy, puerperium, previous inclusion in this study, and inability for the predetermined follow-up. There were no

prophylactic recommendations given to researchers in order to reflect the actual clinical practice in China.

The study protocol was approved by the Ethical Committee at all participating hospitals. Written informed consent was acquired from all patients before inclusion.

#### 2.2. Study design

Patients' demographic, surgical, and clinical laboratory data were collected during hospitalization. Patients stratified as being likely to have DVT by using the modified Wells clinical score [7] were to be examined by bilateral whole-leg ultrasound during hospitalization. Clinically suspected PE was to be identified by lung ventilation/per-fusion scintigraphy, pulmonary angiography, or helical computed tomography.

After entering the study, patients were taught the symptoms and signs of VTE (leg pain, heaviness, edema, redness, dyspnea and chest pain) throughout the study period. To remind them of these symptoms and signs, the patients were regularly contacted by telephone 15 days, 1 month, and 3 months after the operation and asked whether any signs or symptoms of VTE arising. A simple questionnaire comprising name, gender, age and the symptoms and signs of VTE was designed and completed during the telephone call. In the case of onset of any signs or symptoms of VTE during the follow-up, the patients were requested to go to the nearest research unit and objective diagnosis by means of whole-leg ultrasound, lung ventilation/perfusion scintigraphy, pulmonary angiography, or helical computed tomography was demanded.

#### 2.3. Study outcomes

The primary outcome was the incidence of confirmed DVT or PE, or both during the study period. The other study outcomes were the evaluation of risk factors for VTE and the overall mortality at the 3-month follow-up. DVT was defined as DVT which was suspected clinically by using the modified Wells clinical score and subsequently confirmed by bilateral whole-leg ultrasound. PE was defined as PE which was suspected clinically and finally confirmed by lung ventilation/perfusion scintigraphy, pulmonary angiography, or helical computed tomography.

Each episode of VTE was reviewed by an independent event committee using patients' records, ultrasonography reports, venograms, scintigrams, angiograms, and any other accessible materials.

#### 2.4. Statistical analysis

The incidence of VTE was calculated and a subgroup analysis was performed by using chi-square test or Fisher's exact test. Risk factors for the development of VTE were evaluated by the backward binomial logistic regression model. The odds ratio (OR) and the associated 95% CI were calculated. P-values < 0.05 were considered statistically significant. All analyses were conducted using SPSS software (SPSS, Inc.).

#### 3. Results

#### 3.1. Study population

Between June 2013 and June 2015, 5077 consecutive patients were screened at 3 hospitals. We excluded 48 patients owing to absence during the follow-up (40 patients) and refusal to offer informed consent (8 patients). Finally, 5029 patients were enrolled in the analysis.

The study population consisted of 1242 (24.7%) men and 3787 (75.3%) women aged 46.0  $\pm$  12.8 years (mean  $\pm$  SD). The obese patients whose body mass index (BMI) were greater than or equal to 30 kg/m<sup>2</sup> accounted for only 5.6% (283 patients). All patients were treated surgically under general anesthesia. The surgical procedures

included total thyroidectomy (47.9%), residual thyroidectomy (4.7%), lymph node dissection (7.1%), lobectomy (25.3%), and partial thyroidectomy (15.0%). The mean interval from admission to operation was  $3.1 \pm 2.2$  (mean  $\pm$  SD) days, and the mean duration of hospitalization was  $8.4 \pm 3.2$  (mean  $\pm$  SD) days. The postoperative pathological diagnosis consisted of 3692 (73.4%) carcinomas and 1337 (26.6%) benign diseases. No patient received pharmacologic or mechanical prophylaxis. The 3-month follow-up was completed for 99.1% of the cohort. The detail baseline characteristics of the enrolled patients are showed in Table 1.

#### 3.2. Incidence of VTE

The incidence of confirmed VTE was 0.36% (18 events, 95% CI = 0.19% to 0.52%) via bilateral whole-leg ultrasound during the 3-month study period. All 18 cases of confirmed VTEs were DVTs. Furthermore, 83.3% (15/18) of VTE cases occurred during the hospitalization. During the hospitalization, 45 patients were stratified as being likely to have DVT by the modified Wells clinical score, 15 DVTs of whom were confirmed by bilateral whole-leg ultrasound; no PE was suspected clinical-ly. During the follow-up, 57, 23 and 12 patients reported the symptoms or signs of DVT 15 days, 1 month, and 3 months after the operation respectively, 3 DVTs of whom were confirmed by bilateral whole-leg ultrasound 15 days after the operation in the nearest research unit, no patient reported a PE event during follow-up. One (0.03%) patient committed suicide and died. There were no deaths related to VTE.

#### 3.3. Risk factors for VTE

According to the presence or absence of the predefined set of variables on the basis of previous knowledge and scientific interest, we first conducted the univariate analysis and summarized the results in Table 2. Age, BMI, diabetes mellitus, hypertension and site of IVA were identified as significant risk factors; however, sex, smoking, oral contraceptives, surgery duration and malignant disease were not statistically significant risk factors. When the patients were divided into 5 groups

#### Table 1

Patient characteristics (n = 5029).

Characteristics	Number of patients (%)
Age (years)	$46.0 \pm 12.8$
Sex	
Male	1242 (24.7)
Female	3787 (75.3)
BMI (kg/m <sup>2</sup> )	
< 25	3534 (70.3)
≥ 25, <30	1212 (24.1)
≥ 30	283 (5.6)
Diabetes mellitus	598 (11.9)
Hypertension	1313 (26.1)
Smoking	553 (11.0)
Oral contraceptives	147 (2.9)
Surgery type	
Total thyroidectomy	2409 (47.9)
Residual thyroidectomy	236 (4.7)
Lymph node dissection	358 (7.1)
Lobectomy	1272 (25.3)
Partial thyroidectomy	754 (15.0)
Surgery duration (h)	
<1	31 (0.6)
≥1,<2	3193 (63.5)
≥2,<3	1767 (35.1)
≥3	38 (0.8)
Site of IVA	
Left lower limb	3250 (64.6)
Right lower limb	1748 (34.8)
Upper limbs	31 (0.6)
Malignant disease	
Yes	3692 (73.4)
No	1337 (26.6)

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