



Implementation of a pulmonary thromboembolism prophylaxis program in Chinese lung surgery patients: compliance and effectiveness

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Background: Most studies on prophylaxis against pulmonary embolism (PE) after lung surgery have come from the West. Whether such prophylactic programs can be successfully developed in China has not been fully studied.

Methods: A prospective observational trial included 581 Chinese patients receiving lung resection surgery between August 8 and September 12 of 2017. The Caprini score was assessed on the first postoperative day (POD1). For PE prophylaxis, patients with a low score (0–4, n=55) received early ambulation, and those with a high score (≥5, n=526) received early ambulation combined with low-molecular weight heparin (LMWH) injection. PE incidence and the compliance with this protocol was recorded.

Results: Three patients (0.52%) developed PE and all 3 were in the high-risk group, but LMWH was not given (non-compliance). Within the non-compliance patients (n=275), the incidence of PE was 1.09%, higher than that in the compliance patients (0%). The rate of non-compliance with the program was 47.3% (275/581) in the entire cohort. The factors associated with non-compliance were: extended lobectomy performed (9.2% vs. 1.0%, P<0.001); higher volume of postoperative chest drainages (278 vs. 239 mL, P=0.028). The non-compliance group had longer duration of ICU stay (mean of 1.3 vs. 1.1 days, P<0.001); and longer overall hospital stay (mean of 9.7 vs. 8.5 days, P<0.001).

Conclusions: Developing a PE prophylaxis program for patients receiving lung surgery in China contributed to lowering the risk of PE. Failure of compliance in patients with high risk for PE after lung surgery may be linked to worse outcomes.

Keywords: Pulmonary embolism (PE); thoracic surgery; chemoprophylaxis; ambulation; Caprini risk assessment model (RAM)

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1
2 **Introduction**

3 Postoperative pulmonary embolism (PE) can be a
4 devastating postoperative complication and a leading
5 cause of mortality after thoracic surgery (1-3). Although
6 the American College of Chest Physicians (ACCP)

7
8 has published guidelines for prevention of venous
9 thromboembolism (VTE) in non-orthopedic surgical
10 patients in 2012 (4-6), the VTE prophylaxis was not fully
11 implemented all over the world, at least in China (7).
12 The ACCP guidelines include mechanical prophylaxis

13 for low-risk or very low-risk patients, chemoprophylaxis
 14 or mechanical prevention for middle-risk patients and
 15 chemoprophylaxis combined with mechanical prevention
 16 for high-risk patients (6). The assessment of such risk
 17 often involves the Caprini VTE risk assessment model
 18 (RAM), championed by Joseph Caprini (8-10) and others
 19 (11,12). A program of early postoperative mobilization
 20 and prophylaxis based on an adjusted Caprini RAM has
 21 been applied in thoracic patients at Boston Medical Center
 22 (BMC) and found to significantly reduce the likelihood of
 23 VTE complication after surgery (13).

24 However, more than half (53.91%) of surgeons in China
 25 do not follow VTE prophylaxis guidelines after lung cancer
 26 resection, and continue to make decisions on the method
 27 and duration of VTE prophylaxis depending on their own
 28 clinical experience only (14). On the other hand, it is not
 29 known whether following guidelines designed for Western
 30 populations is necessarily beneficial in Chinese populations.
 31 It is possible that Chinese patients may require different
 32 VTE prophylaxis practices. PE actually is an uncommon
 33 event in the Asian population judging from the Japanese
 34 report (15). In this report, death from PE was observed
 35 in only two patients among 30,597 (0.007%) lung cancer
 36 cases undergoing lobectomy in Japan. In our own hospital,
 37 we have observed a lower overall PE incidence in patients
 38 after lung cancer resection compared to Western reports
 39 (4,16) and hence a lower dose of thrombolytic treatment
 40 has traditionally been used for massive or sub-massive PE
 41 compared to Western practices (17-20). Therefore, we
 42 hypothesized that preventative measures for postoperative
 43 PE specific to Chinese patients may be needed which
 44 are distinct from Western guidelines. In this study, we
 45 developed a simple prophylaxis program against pulmonary
 46 thromboembolism after lung surgery using the Caprini
 47 RAM for risk stratification. Our objective was to investigate
 48 if such a program may contribute to lowering the risk
 49 of PE, and whether it could be implemented with good
 50 compliance in a Chinese hospital. We present the following
 51 article in accordance with the STROBE guideline checklist
 52 (available at <http://dx.doi.org/10.21037/jtd-20-690>).

53

54 **Methods**

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56 **Patients**

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58 The study was conducted in accordance with the
 59 Declaration of Helsinki (as revised in 2013). All consecutive

60 adult patients who received lung resection surgery for lung
 61 cancer or inflammatory lung disease by the Department of
 62 Thoracic Surgery of Shanghai Pulmonary Hospital were
 63 eligible for this study. Informed consent was obtained at the
 64 time of admission. The cohort enrollment began on 8 August
 65 2017 and ended at 12 September 2017. Inclusion criteria
 66 included: adult patients able to give informed consent; major
 67 lung resection performed via open or minimally invasive
 68 surgical approaches; and surgery with curative intent for
 69 lung cancer or inflammatory lung diseases. Exclusion criteria
 70 included: history of inferior vena cava filter placement;
 71 history of anti-coagulation treatment; presence of deep
 72 venous thrombosis (DVT) found during the preoperative
 73 check-up; and those patients lost to follow-up. Routine lower
 74 limb Doppler ultrasonography was performed in all patients
 75 before surgery, and those diagnosed with DVT were referred
 76 for further treatments before surgery.

77

78 *The Caprini RAM*

79

80 All patients were scored using a Caprini RAM (10-13,21).
 81 The variables included age, body mass index (BMI), surgery,
 82 malignancy, previous medical history, existing symptoms,
 83 and so on. We omitted consideration of the followings
 84 because of technical limitations and their rarity in Chinese
 85 patients: Prothrombin 20210A; factor V Leiden; lupus
 86 anticoagulant; and anticardiolipin antibodies. The Caprini
 87 score of each patient was assessed and recorded by two
 88 attending ICU doctors at 8 a.m. of the first postoperative
 89 day (POD1). Then the patients were classified into low (0-4)
 90 or high (≥ 5) PE risk level based on the Caprini score.

91

92 *Postoperative thromboprophylaxis protocol*

93

94 Our prophylaxis program for PE was initiated on 8 August
 95 2017. Before that time, thromboprophylaxis measures—
 96 namely intra-operative management and pre-operative
 97 low-molecular weight heparin (LMWH)—were only used
 98 sporadically according to each surgeon's own preferences.
 99 With implementation of our program, all postoperative
 100 patients were admitted to the thoracic postoperative
 101 intensive care unit (ICU) immediately after surgery and
 102 were observed there for at least 24 hours. Our prophylaxis
 103 program included two elements: (I) early ambulation
 104 defined as mobilizing out of bed started no later than
 105 24 hours after surgery; (II) early chemoprophylaxis with
 106 LMWH injection subcutaneously once daily, started no

107 later than 24 hours after surgery. Early ambulation alone
 108 was used for patients at low risk (Caprini 0–4), early
 109 chemoprophylaxis plus early ambulation was for patients
 110 at high risk (Caprini ≥ 5). Patients who for whatever reason
 111 only received LMWH after discharge from ICU back to
 112 the general ward (i.e., after 24 hours from surgery) were
 113 defined as having received late chemoprophylaxis. Use of
 114 the program in any patient is postponed or cancelled if any
 115 of the following occurred: total chest tube drainage of more
 116 than 500 mL within 24 hours after surgery; major bleeding
 117 encountered during operation; surgeon in charge identified
 118 any clinical contraindication (such as development of a
 119 thoracic hematoma). All chemoprophylaxis treatment was
 120 used only during hospitalization, and no outpatient PE
 121 prophylaxis was prescribed after discharge.

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123

124 *Data collection and patient follow-up*

125 Data for all patients were prospectively collected after
 126 surgery. In addition, patients were followed up twice at 30
 127 and 60 days after surgery by phone call. At any time during
 128 in-hospital stay, PE-associated symptoms or clinical signs
 129 were identified, including chest pain, shortness of breath,
 130 hemoptysis, cyanosis, decrease of SpO₂ (oxyhemoglobin
 131 saturation by pulse oximeter) or unexplained blood pressure
 132 decrease. If these were identified, the patient would receive
 133 computed tomographic pulmonary angiography (CTPA).
 134 Then if PE was diagnosed, the patient would receive
 135 anti-coagulation or thrombolytic treatment according to
 136 hospital guidelines. During the follow up, the patients
 137 were requested if they had some problems of chest pain,
 138 shortness of breath and if they had visited local doctors
 139 routinely and what about the routine test results. Our
 140 nurses requested the patients over phone and recorded the
 141 answers in the formal questionnaire.

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143

144 *Compliance analysis*

145 To assess risk factors for non-compliance with the
 146 prophylaxis program, we used multivariable logistic
 147 regression with age, sex, surgical procedures, pathology,
 148 postoperative chest drainages included. Then we performed
 149 propensity-score matching with the identified variables
 150 to pair on a 1:1 bases patients in the high-risk group in
 151 whom the prophylaxis was used according to the program
 152 (compliance) with those in whom the program was not
 153 followed (non-compliance).

Statistical analysis

We used SPSS software (IBM Corp. Released 2017. IBM
 SPSS Statistics for Windows, Version 25.0. Armonk,
 NY: IBM Corp.) to perform statistical analysis. Results
 were presented as means \pm standard deviation (SD). The
 independent-samples *t*-test was used for continuous
 variables. The Chi-square test and the Fisher's exact test
 was used for categorical variables. Spearman correlation
 and multivariable logistic regression was performed for
 prediction analyses and to explain the relationship between
 variables. A P value <0.05 was considered statistically
 significant.

Results

Patients

In total, 620 postoperative patients were identified as
 potentially eligible for study from August 8 to September
 12 of 2017 (*Figure 1*). Exclusions included: 17 patients who
 received non-lung surgery; 18 patients lost during follow-
 up, and 4 patients found to have DVT before surgery.
 Finally 581 patients were enrolled. As shown in *Table 1*, sub-
 lobar resection (n=188), lobectomy (n=368) and extended
 lobectomy (n=25) were performed for lung cancer or
 inflammatory lung diseases in 433 (74.5%) and 148 (25.5%)
 cases respectively. Of 581 lung surgery patients, 55 cases
 were stratified as low PE risk level, 526 cases were high PE
 risk level.

At follow-up up to 60 days after surgery, three
 patients (0.52%) were found to have developed PE. All
 three patients developed PE during their postoperative
 hospitalization. These three PE cases all belonged to high
 risk group. In all three patients, there was non-compliance
 with the prophylaxis program: none was administered
 with early chemoprophylaxis, and two of them performed
 early ambulation. As for treatment, one patient (Caprini 6)
 received low-dose thrombolytic treatment, but died. The
 other two patients (Caprini 9 and 10, respectively) were
 alive, and received anti-coagulation treatment with LMWH
 twice a day. No major bleeding occurred with the use of
 chemoprophylaxis in all patients in this study.

Compliance versus non-compliance

The rate of compliance with the program was 52.7%
 (306/581) in the entire cohort. Among 55 patients in

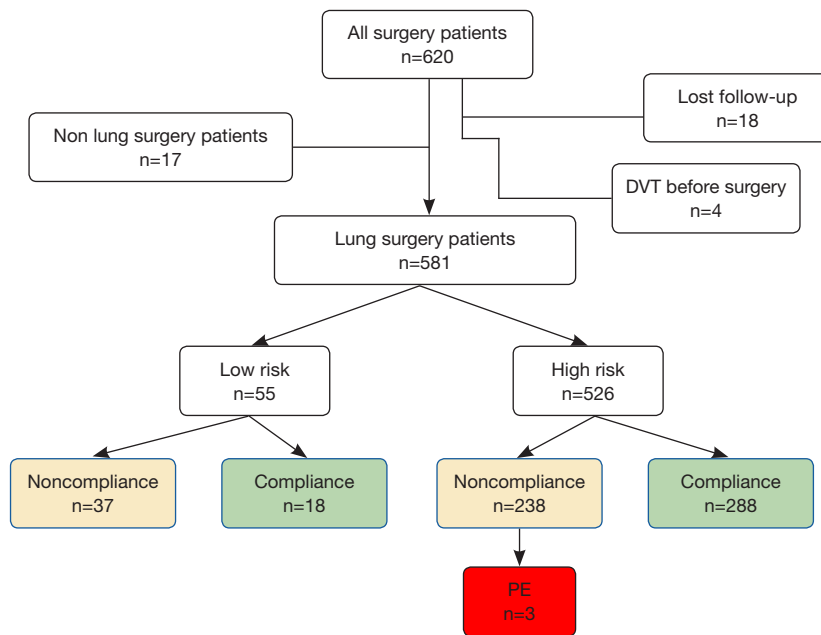


Figure 1 An overview of all patients.

Table 1 Baseline characteristics

Characteristics	Number (n=581)
Age (y)	58.8±11.2
Male, n (%)	288 (49.6)
BMI (kg/m ²)	23.3±3.2
Pathologic diagnosis, n (%)	
Malignant	433 (74.5)
Benign	148 (25.5)
Surgical procedure, n (%)	
Sublobar resection	188 (32.4)
Lobectomy	368 (63.3)
Extended lobectomy	25 (4.3)
Length of stay in ICU (d)	1.2±0.6
Length of stay in hospital (d)	8.8±3.6
PE risk grouping, n (%)	
Low (0–4)	55 (9.5)
High (≥5)	526 (90.5)

BMI, body mass index; ICU, intensive care unit; PE, pulmonary embolism.

202 the low risk group, only 18 (32.7%) had full compliance
 203 with our protocol, but PE did not occur in this group.
 204 Amongst patients in the high-risk group, 288 (54.8%)
 205 had full compliance with the program, but 238 (45.2%)
 206 did not. As shown in Table 2, the rate of PE was 0% in the
 207 full compliance subgroup, compared to 1.3% in the non-
 208 compliance subgroup (P=0.092). Within the high-risk
 209 group, the occurrence of PE was related to non-compliance
 210 (r=0.08, P=0.056).

211 Patients in the non-compliance subgroup of high-risk
 212 patients had: higher frequency of extended lobectomy (9.2%
 213 vs. 1.0%, P<0.001); higher volume of chest drainage on
 214 POD1 (mean of 278 vs. 239 mL, P=0.028); longer duration
 215 of ICU stay (mean of 1.3 vs. 1.1 days, P<0.001); and longer
 216 overall hospital stay (mean of 9.7 vs. 8.5 days, P<0.001)
 217 (Table 2). There were no differences in the age, sex and
 218 pathologic diagnosis distribution between the compliance
 219 and non-compliance subgroups. Multivariable logistic
 220 regression for the high-risk group showed that the main
 221 factors influencing compliance with the program were:
 222 surgical procedure and POD1 chest drainage (Table 3).

223 Next, we would like to balance these two factors within
 224 high risk group. We performed propensity score matching
 225 with surgical procedure and chest drainage included and

Table 2 Compliance vs. non-compliance within the high-risk group

Variable	Compliance (n=288)	Non-compliance (n=238)	P
Age (y)	60.0±10.5	60.6±9.6	0.51
Male, n (%)	150 (52.1)	121 (50.8)	0.78
Surgical procedure, n (%)			<0.001
Sub-lobar resection	86 (29.9)	57 (23.9)	
Lobectomy	199 (69.1)	159 (66.8)	
Extended lobectomy	3 (1.0)	22 (9.2)	
Pathologic diagnosis, n (%)			0.36
Benign	60 (20.8)	42 (17.6)	
Malignant	228 (79.2)	196 (82.4)	
Chest tube drainage (mL)			
POD1	239±165	278±227	0.028
POD2	254±184	263±257	0.63
POD3	145±128	166±151	0.095
Length of stay in ICU (d)	1.1±0.3	1.3±0.7	<0.001
Length of stay in hospital (d)	8.5±3.1	9.7±4.0	<0.001
PE cases, n (%)	0	3 (1.3)	0.092

POD, postoperative day; ICU, intensive care unit; PE, pulmonary embolism.

Table 3 The multivariable logistic regression of compliance in the high-risk cohort

Factors	Odds ratio (OR)	95% CI for OR	P
Age (y)	0.998	0.980–1.015	0.81
Sex	0.826	0.578–1.181	0.30
Surgical procedure	0.598	0.420–0.853	0.005
Pathologic diagnosis	0.961	0.610–1.516	0.87
POD1 chest drainages (per 100 mL)	0.911	0.830–1.0	0.049

POD1, the first postoperative day; CI, confidence interval.

226 paired 238 patients in the compliance subgroup with 238
 227 in the non-compliance subgroup. The standardized mean
 228 difference before matching was 0.025, and after matching it
 229 was 0.013. After matching, we found that non-compliance

Table 4 Matched cohort within the high-risk group

Variable	Compliance (n=238)	Non-compliance (n=238)	P
Age (y)	59.9±10.3	60.6±9.6	0.46
Male, n (%)	129 (54.2)	121 (50.8)	0.46
Surgical procedure*, n (%)			<0.001
Sub-lobar resection	55 (23.1)	57 (23.9)	
Lobectomy	180 (75.6)	159 (66.8)	
Extended lobectomy	3 (1.3)	22 (9.2)	
Pathologic diagnosis, n (%)			0.42
Benign	49 (20.6)	42 (17.6)	
Malignant	189 (79.4)	196 (82.4)	
Chest tube drainage (mL)			
POD1*	257±160	278±227	0.24
POD2	259±189	263±257	0.83
POD3	157±130	166±151	0.52
Length of stay in ICU (d)	1.1±0.3	1.3±0.7	<0.001
Length of stay in hospital (d)	8.7±3.1	9.7±4.0	0.001
PE cases, n (%)	0	3 (1.3)	0.25

*, these variables were included when we performed the propensity score matching. POD, postoperative day; ICU, intensive care unit; PE, pulmonary embolism.

was linked to: surgical procedure performed; length of stay
 in ICU; and length of in-patient hospital stay (*Table 4*).

Discussion

It has been more than 5 years since the ACCP published the prevention guidelines for VTE in non-orthopedic surgical patients (6). However, in China, similar guidelines for PE in thoracic surgical patients have not emerged (14). In this study, we adopted the Caprini RAM for stratifying PE risk in Chinese lung surgery patients, and hence to allocate them to receive a new, simple-to-follow PE prophylaxis program. We found an overall rate of PE of 0.52% in our series. However, the rate of compliance with using the program was poor at only 52.7% overall. In comparison, a study from the US reported a compliance rate of 96% and the PE incidence was 2.3% (13).

247 The low rate of PE amongst Chinese patients, also
 248 Japanese patients, after major surgery has been observed
 249 and speculated upon before (15-17). Our study appears to
 250 corroborate this. But it is still possible that our study may
 251 have underestimated the rate of actual PE as investigations
 252 were only done in patients developing symptoms or signs
 253 suggestive of PE. Also, we only considered PE in this
 254 study, although postoperative VTEs may include DVT
 255 without embolism to the chest. It has indicated that routine
 256 lower limb Doppler ultrasonography before patients were
 257 discharged might provide a different picture of VTE
 258 incidence in thoracic surgery patients (22).

259 The low rate of compliance is more striking. However,
 260 it is difficult to say exactly what the reason for such low
 261 compliance may be. The probable major reason in this
 262 study was the extent of the surgical procedures which
 263 was consistent with other studies (23). We note that the
 264 volume of POD1 chest drainage tended to be higher in
 265 the non-compliance subgroup than in the compliance
 266 subgroup. It is possible that surgeons in our hospital may
 267 approach postoperative drainage volumes with greater
 268 conservatism in patients after major lung surgery, and may
 269 be more reluctant to use LMWH in patients with relatively
 270 higher drainage. It is noted that non-compliance was also
 271 correlated with a longer ICU stay and a longer overall
 272 hospital stay. It is difficult to be certain in an observational
 273 study such as this whether the poor compliance was the
 274 cause or the result of any events that led to longer stays. It
 275 is entirely possible that multiple factors—including surgical
 276 training and culture—may also play a role. While in
 277 another study also from US which is quite similar with ours,
 278 the compliance rate was 60.5% and only 1 case occurred PE
 279 among 522 patients (23). They draw a conclusion that their
 280 prophylaxis program was safe and feasible. Although we had
 281 a lower compliance rate, PE incidence correlated with non-
 282 compliance in a very close to significance P value, we can
 283 also deem that our prophylaxis program was effective.

284 The importance of compliance, however, seems to be
 285 reaffirmed by this study. In Chinese patients with high
 286 risk for PE after lung surgery, non-compliance with the
 287 prophylaxis is now confirmed to be linked to higher rate of
 288 postoperative PE, even though the overall rate is lower than
 289 in the West. This further strengthens the argument that
 290 VTE prophylaxis needs to be implemented in Chinese lung
 291 surgery patients, and better effort should be made to ensure
 292 good compliance.

293 A non-random design of this study was the main
 294 limitation. Ideally, the effect of the prophylaxis program

295 should be assessed by randomizing patients to receive or
 296 not receive it. In this study, the separation of patients into
 297 groups who did or did not receive prophylaxis was done by
 298 considering whether or not the program was fully followed
 299 (compliance versus non-compliance). Although this still
 300 achieved the result that there were two groups of fairly
 301 evenly matched patients who did or did not receive the
 302 program, the compliance/non-compliance dichotomization
 303 in our study potentially introduces confounding variables
 304 that may have biased who received the program fully and
 305 who did not. We performed propensity-score matching to
 306 try to minimize this concern, but we acknowledge that even
 307 this is not a substitute for a future randomized study.

308 In summary, our study demonstrated that implementing
 309 a PE prophylaxis program for lung surgery patients in
 310 China contributed to lowering the risk of PE but may be
 311 hindered by a low rate of compliance. Nonetheless, failure
 312 of compliance in patients with high risk for PE after lung
 313 surgery may be linked to worse outcomes, and hence there
 314 is a real need to develop and enforce such a program.
 315

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 321

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 337

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 341 appropriately investigated and resolved. The study was
 342 conducted in accordance with the Declaration of Helsinki

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 344 Ethics Committee of Shanghai Pulmonary Hospital. The
 345 Institutional Review Board approved submission and
 346 publication of this work and informed patient consent was
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349
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