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Stratified Prophylaxis of Deep Venous Thrombosis in Surgical Patients Based on Caprini Risk Assessment: A Pilot Study

Jiaojiao Gu, Miaoxia Chen, Ling Zou, Xia Lin, Zhaolan Ou, Xiaoqing Huang, Chunxiao Luo, Yexiang Yang

Hepatobiliary Surgery Department, Third Affiliated Hospital of Sun Yat-sen University, Guangzhou, China
Email: gujiaoj@mail2.sysu.edu.cn

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Abstract

BACKGROUD: Venous thromboembolism (VTE) including DVT and pulmonary embolism (PE) can be a devastating complication in postoperative patients which is also considered the most likely to be prevented. The proper assessment and effective identification of high risk factors of DVT are the basis for its prevention. We used the Caprini risk assessment model (Caprini RAM) based on many researches about the validation of DVT risk assessment model, and combined the recommendations reported in American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (9th) and Chinese Orthopaedics Association guideline, to give surgical patients stratified prophylaxis. **STUDY DESIGN:** Between April 2016 and December 2016, we conducted a controlled trial study in 4 surgical departments including Gynecology Department, Joint Surgery, Spinal Surgery and Urology Surgery. 764 patients were included in control group, and 772 patients were included in intervention group. We used the original assessment and prevention methods in control group, while applied the stratified prophylaxis based on Caprini risk assessment level in intervention group. The incidence of DVT was analyzed using chi-square test, while patients' hospital day was analyzed by independent t-tests. **RESULTS:** There was significantly difference in incidence rate of DVT between the two groups (13.09‰ vs. 2.59‰, $P < 0.05$), while the difference in hospital day was not significantly (10.63 ± 5.80 vs. 10.29 ± 5.18, $P > 0.05$). Most of the surgical patients were with moderate or high-risk (64.93%). **CONCLUSIONS:** Nurses could identify DVT risk factors in surgical patients using the Caprini risk assessment scale, and apply targeted stratified prophylaxis according to risk level. This model makes DVT risk assessment and intervention process more standardized and effective. It can al-

so reduce incidence rate of DVT significantly.

Keywords

DVT, VTE, Caprini, Prophylaxis

1. Introduction

Venous thromboembolism (VTE), including DVT and pulmonary embolism (PE), is a common complication in surgical patients that can cause morbidity and mortality. Approximately 900,000 cases of DVT and PE occur annually in the United States and one-third lead to patient's death [1]. During the acute phase of DVT, 10% to 40% of patients will develop PE, with a mortality rate of 10% to 20% [2]. Due to numerous factors including postoperative bed rest, obesity, hypercoagulable conditions, and coagulation activation from venous, and surgical trauma, surgical patients are at increased risk of DVT. Strong evidences demonstrate that DVT prophylaxis can reduce the DVT incidence [3] [4] [5], but more than half of the hospitalized patients at high risk do not receive DVT prophylaxis world widely [6] [7], and about how to choose accurate prophylaxis for different patients, less of studies mentioned. Zhou HX *et al.* [8] reported that in 347 VTE patients, only 38 (11%) of them received thromboprophylaxis. Accurate DVT risk assessment can help to change this situation.

Accurate risk assessment helps clinicians to identify both high and low-risk patients. Therefore, DVT prophylaxis decisions can be made for an individual patient based on unique risk profile [9]. Caprini *et al.* [10] introduced a risk assessment scheme to estimate DVT risk in the general surgical population. The Caprini risk assessment model is a weighted risk stratification tool which summarizes individual risk factors to place patients into 4 categories: "low risk" (0 - 1 points), "moderate risk" (2 points), "high risk" (3 - 4 points), and "highest risk" (≥5 points) [10]. The model contains 31 risk factors, and different risk factors carry different point values according to the contribution to DVT. The Caprini RAM had been validated in many studies in samples of malignant abdominal tumors [2], gynecologic oncology [11], thoracic surgical [12], plastic and reconstructive surgery [9] patients and so on. It is a practical and effective tool to assess the risk of VTE. American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (9th) and Chinese Orthopaedics Association (COA) guideline also recommended the use of it in surgical patients [13] [14].

In addition, all of the previous studies focused on the validation of the Caprini RAM. Few of them concerned the applications of prophylaxis based on it. Therefore, we combined the Caprini risk assessment model and guidelines in ACCP-9 and COA to give surgical patients stratified prophylaxis in our hospital, in order to confirm whether this DVT risk assessment and prophylaxis model can be effective in Chinese surgical patients.

2. Methods

2.1. Study Design

We performed a clinical trial study among 4 surgical departments including Gynecology Department, Joint Surgery, Spinal Surgery and Urology Surgery at the Third Affiliated Hospital of Sun yat-sen University (an 1800-bed comprehensive teaching hospital, Guangzhou, Guangdong province, China) between April 2016 and December 2016. Patients between April and August 2016 were recruited in the control group, while patients between September and December 2016 were recruited in the intervention group. We used the original assessment and prevention methods in control group, while applied the stratified prophylaxis based on Caprini risk assessment level in intervention group.

Experienced nurses in each department were trained to carry out this research, and in the intervention group, 4 nurse managers conducted the quality control every month, to inspect the DVT risk factors assessment rate and the implementation rate of DVT prophylaxis, in order to improve the quality and reliability of this research.

2.2. Participants

A total of 1536 participants voluntarily joined the study and provided written informed consent. We included 764 hospitalized surgical patients in the control group, 772 patients in the intervention group.

Eligible cases included conscious patients admitted to the surgical department for 2 or more days, 18 years or older. Participants were excluded if they met any of the following criteria: 1) diagnosis of VTE; 2) direct admission for end-of-life or palliative care.

3. Interventions

3.1. Control Group

In control group, participants received unsystematic DVT risk assessment, for patients older than 60 years, undergoing major surgery, and confined to bed more than 3 days, the clinicians and nurses would give them DVT prophylaxis such as health education, clinical observation, intermittent pneumatic compression (IPC), elastic stockings, or low-molecular-weight heparin.

3.2. Intervention Group

In intervention group, nurses used Caprini RAM to assess DVT risk factor at the day of admission, operation, occurrence of DVT positive signs and syndromes, and discharge, to get the patients' DVT risk level. Experts formulated guidelines of DVT prevention for nonorthopedic surgical patients in ACCP-9. Guidelines of DVT prevention for 3 kinds of major orthopedic surgery including total hip arthroplasty, total knee arthroplasty and hip fractures surgery were revised by experts in Chinese Orthopaedics Association in 2016. Both the guidelines rec-

ommended using Caprini RAM before making decisions of DVT prophylaxis. Combined Caprini RAM and the 2 guidelines, we formulated the stratified prophylaxis (Table 1). Nurses reported patients' DVT risk level to physicians, and formulated prophylaxis strategy together. The physicians judged if patients had hemorrhagic tendency based on their blood test and operation conditions, in order to decide whether using anticoagulant during perioperative period. Nurses recorded patients' risk level and prophylaxis in manuscript.

3.3. Outcomes

The primary outcome was incidence of DVT during hospitalization and diagnosis of DVT required confirmation via Doppler ultrasound when patients were with DVT positive signs and at the day of discharge. The secondary outcome was hospital day; it was recorded at patients' discharge day.

3.4. Statistical Analysis

Continuous variables with a normal distribution were described as means with standard deviations, and group comparisons were performed with the t-test; continuous variables with skewed distribution were presented as median values with interquartile ranges. Discrete variables such as incidence of DVT were presented as frequencies and percentages, and group comparisons were performed using the chi-square.

The criterion for statistical significance was set at an α of 0.05 and all P values were based on 2-sided tests. IBM SPSS Statistics, version 20.0 (IBM Corp., Armonk, NY) was used for all statistical analyses.

Table 1. DVT Prophylaxis according to Caprini RAM.

DVT risk level	Caprini score	Prophylaxis
Low	0 - 1	Early ambulation;
Moderate	2	(1) Dirigation including ankle pump movement, straight-leg-raising movement; (2) Basic prophylaxis such as early ambulation, raising the lower extremities 30 degrees, keeping the lower extremities warming and health education for patients; (3) IPC.
High	3 - 4	(1) Dirigation; (2) Basic prophylaxis; (3) For patients who were not at high risk of bleeding complication: low-molecular-weight heparin (LMWH), or IPC; (4) For patients who were at high risk of bleeding complication: IPC.
Highest	≥5	(1) Dirigation; (2) Basic prophylaxis; (3) For patients who were not at high risk for bleeding complication: LMWH, and IPC or ES; (4) For patients who were at high risk for bleeding complication: IPC or ES; (5) For patients in whom both LMWH and unfractionated heparin are contraindicated or unavailable and who are not at high risk for bleeding complication: low-dose aspirin, fondaparinux, and IPC or ES.

4. Results

The study population consisted of 1536 Chinese patients, 764 patients in control group were comparable with the 772 patients in intervention group in baseline age, sex, smoking history, and no statistically significant differences were observed between the 2 groups, but in department, there was significant difference between the 2 groups (Table 2). The distribution of DVT risk level after operation is as showing in Table 3.

There was a statistically significant difference in the incidence of DVT between the 2 groups (13.09‰ vs 2.59‰, $P < 0.05$), but in each department, no statistically significant difference was observed ($P > 0.05$) (Table 4).

The average length of hospital stay in control group was 10.63 days, in intervention group, it was 9.98 days, and no statistically significant difference was observed ($P > 0.05$) (Table 5).

Quality Control

During the research, quality control nurses found nurses omitted risk factors such as on bed rest or restricted mobility, other risk factors, minor surgery (less than 45 minutes) the most at the first 2 weeks. And 2 patients' risk assessment was omitted after operation. Otherwise, passive activity and anticoagulation had the lowest implementation rate. The reason may be that some nurses didn't grasp the time and method of using the assessment table.

We formulated directions for use of Caprini RAM, and trained nurses in each department to use it correctly. Also, quality control nurses continued to check the assessment and prophylaxis process every month. By the quality control, the DVT risk factors assessment rate was increased from 63.64% at the first 2 weeks to 89.39% at the 3thd month; and implementation rate of DVT prophylaxis was increased from 86.73% to 91.68%.

Table 2. Baseline characteristics of patients in control and intervention group.

Characteristics	Intervention group (n = 772)	Control group (n = 764)	P
Age (years)	41.60 ± 14.00	41.67 ± 15.07	0.981
Gender (n, %)			
Male	271 (35.10%)	292 (38.22%)	0.205
Female	501 (64.90%)	472 (61.78%)	
Smoking history (n, %)			
Yes	182 (23.58%)	207 (27.09%)	0.113
No	590 (76.42%)	557 (72.91%)	
Department (n, %)			
Joint Surgery	202 (26.16%)	231 (30.24%)	<0.001
Spinal Surgery	101 (13.08%)	75 (9.82%)	
Gynecology Department	305 (39.51%)	208 (27.23%)	
Urology Surgery	164 (21.24%)	250 (32.72%)	

Table 3. Distribution of DVT risk after operation in intervention group (n, %).

	Joint Surgery	Spinal Surgery	Gynecology Department	Urology Surgery	Total
Low-risk	28 (13.86%)	8 (7.92%)	85 (27.87%)	40 (24.39%)	161 (20.91%)
Moderate-risk	49 (24.26%)	23 (22.77%)	122 (40.00%)	77 (46.95%)	271 (35.19%)
High-risk	80 (39.60%)	52 (51.49%)	66 (21.64%)	32 (19.51%)	230 (29.79%)
Highest-risk	45 (22.28%)	18 (17.82%)	32 (10.49%)	15 (9.15%)	110 (14.25%)
Total	202	101	305	164	772

Table 4. Comparison of DVT incidence between control and intervention group (n).

Diagnosed with DVT	Joint Surgery		Spinal Surgery		Gynecology Department		Urology Surgery		total	
	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention
YES (n)	4	1	1	0	4	1	1	0	10	2
NO (n)	227	201	74	101	204	304	249	164	754	770
χ^2	1.444		1.354		3.260		3.803		5.460	
P	0.230		0.245		0.071		0.079		0.019	

Table 5. Comparison of hospital day between control and intervention group.

	Hospital day ($\overline{x} \pm s$)	t	P
Control group	10.63 ± 5.80	1.208	0.227
Intervention group	10.29 ± 5.18		

5. Discussion

VTE is a common cause of preventable death in surgical patients [15]. Although a high risk of DVT complications was exhibited in surgical patients, the administration of thromboprophylaxis was still not fully performed [16]. Assessment is the first step of DVT prophylaxis, and individualized DVT risk stratification allows risk to be assessed based on the patient's unique factors. Caprini risk assessment model recommended by American College of Chest Physicians and COA has been validated in western hospitalized patients [8] [17]. Researchers also proved that Caprini RAM can be used to effectively stratify hospitalized Chinese populations into DVT risk categories based on individual risk factors [8] [16] [18]. Compared to the Padua RAM, Caprini RAM could distinguish more high-risk patients, and has the higher sensitivity, positive and negative predictive value, and higher prediction accuracy [16]. Optimal thromboprophylaxis must consider both the risks of DVT based on risk assessment and bleeding complications as well as the values and preferences of individual patients [15].

In our study, stratified prophylaxis based on Caprini RAM was supplied to surgical patients, and the results demonstrated that this model could decrease the incidence of DVT in hospitalized surgical patients. Caprini RAM was usually recommended in the evaluation of surgical patients [10] [17] [19]. Among the factors, there are several surgeries related factors such as minor surgery, planned

major surgery, elective hip or knee joint replacement surgery, confined to a bed, current or past malignancies, central venous access or PICC. So it can estimate the risk level of postoperative patients exactly, and predict the risk of DVT recurrence. Based on the risk level, and consider patients' bleeding complication risk, clinicians can choose more accurate and targeted prophylaxis for patients. Otherwise, the model made the DVT prevention more standardized and practical, by following the model according to the process, nurses and physicians can assess patients' DVT risk and its change, and estimate their symptom and syndrome in time, in order to adjust prophylaxis, which can increase the effectiveness of the DVT prophylaxis.

However, in each department, no statistically difference was observed. This situation may be related to small sample size in each department and short time of the study. And difference of the hospital day between the 2 groups was not statistically significant. That may because the incidence of DVT was not very high in both groups, and the therapy of the DVT patients did not cause significant increase of average hospital day.

The risk level of patients after operation in our study was most moderate or high (64.98%), which demonstrated the necessary of DVT prevention in surgical patients. Patients in Gynecology Department and Urology Surgery were most in low or moderate-risk level (67.87%, 71.34%), this result was in accord with incidence of VTE reported by Giancarlo (2.0% in gynecologic surgery, and 0.87% in urologic surgery) [20]. That is because the development of minimally invasive surgery and Fast Track Surgery decrease operation duration, postoperative bed time and so on, which can reduce the assessment score. However, in Joint Surgery and Spinal Surgery, patients' risk level was most moderate or high (63.86%, 74.26%), the situation may relate to complexity of orthopedics operation, patients' trauma, plaster cast, postoperative braking, confined to bed, paralysis and so on, which can increase patients' assessment score. This result demonstrated that in different department, DVT prevention had different focuses.

This research is associated with several limitations. First, it was not a randomized controlled trial; we used only convenience sampling and inclusive criteria to divide patients into 2 groups by date. If we can do random allocation, our findings would be more robust. Second, we conducted this pilot study only in 4 surgery departments from one hospital. In future, we should spread this stratified prophylaxis in other surgical departments and other hospitals to validate its effectiveness on preventing DVT. Third, the research time was not very long, only 9 months, and the sample size was small in each department. If we extend the research time and enlarge the sample size, our findings would be more persuasive.

6. Conclusion

DVT stratified prophylaxis based on Caprini RAM and guidelines is effective, simple and easy to do. But because this was a pilot study, continued long-term

RCTs need to conduct in other surgical population in different hospitals in order to validate the model's effectiveness.

Author Contributions

Study conception and design: Miao-xia Chen, Jiao-jiao Gu;

Acquisition of data: Lin Zou, Xia Lin, Zhao-lan Ou, Chun-xiao Luo, Ye-xiang Yang;

Analysis and interpretation of data: Jiao-jiao Gu;

Drafting of manuscript: Jiao-jiao Gu;

Critical revision: Miao-xia Chen.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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