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Original article

Frequency of deep vein thrombosis among hospitalized non-surgical Japanese patients with congestive heart failure



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ABSTRACT

Purpose: Congestive heart failure (CHF) is one of the risk factors for deep vein thrombosis (DVT) according to the Japanese guidelines for DVT treatment and prevention. The purpose of this study is to estimate the frequency of DVT among hospitalized CHF patients, since there have been only limited DVT data in Japanese CHF patients.

Methods: Patients enrolled in the study were with risk factors for DVT listed in the guidelines as well as with acute exacerbation of CHF, bed rest for at least 4 days, and aged 60 or above. Patients treated by physical prophylaxis or anti-platelet medication were included, while patients treated by any anticoagulant medicines were excluded. Patients with surgery or injury within 3 months before the hospitalization or diagnosed clinically or with obvious past history as having DVT at hospitalization were excluded. The presence of DVT in the eligible patients was determined by ultrasonography and the images were evaluated by an independent central evaluation committee.

Results: Forty-four patients were enrolled in the study including 19 males and 25 females. The mean age was 79.0 ± 10.6 years, and the mean duration of bed rest was 8.9 ± 3.2 days. Out of these 44 patients, DVT was detected in 15 (34%) patients. Eight patients were on treatment with physical prophylaxis but DVT was still detected in two patients. Furthermore, 12 out of the rest of the patients were treated by anti-platelet agents and were still with DVT in 3 patients.

Conclusion: When evaluated ultrasonographically, the frequency of DVT in hospitalized non-surgical Japanese patients with CHF was approximately 35%. DVT occurred in 25% of patients treated by physical prophylaxis or anti-platelet agents. The results suggest that Japanese hospitalized patients with CHF have a high risk of DVT and thus can be recognized to have potential benefit by preventing and treating DVT according to the guidelines.

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Introduction

In Japan, the frequency of deep vein thrombosis (DVT) was recognized as being lower than that overseas [1]. However recent reports suggest that the frequency of DVT in Japanese can be assumed similar to that in Westerners. The frequencies of DVT in

Japanese post-operative patients with hip replacement surgery and knee replacement arthroplasty are 27.4% and 50.0%, respectively [2]. In Westerner, the frequencies are 42–57% for hip replacement surgery and 41–85% for knee replacement arthroplasty [3].

It is recognized that the frequency of VTE in specific patient population of medical practice is higher than that of surgical patients with mild-to-moderate risks, although the reported frequencies have large variance. In some studies outside of Japan, the frequencies of DVT were reported to be 10–26% of general in-hospital patients [4–6]. Especially in patients with CHF, Nicolaides et al. [7] reported the frequency reached to 40%. Based on these studies, the approaches for primary prevention of VTE have already been introduced since more than 20 years ago in USA and Europe. Currently, the requirement of prevention for VTE is widely recognized not only for post-operative patients but also for hospitalized patients in medical practice [8].

The current Japanese prevention guideline [9] recommends primary prevention to some specific internal diseases including congestive heart failure (CHF). Ota et al. [10] reported that NYHA class related to increase in the VTE risk particularly in patients with an extremely high risk for NYHA class IV in Japan. That is the reason why the condition of CHF with NYHA III or IV is targeted by the current prevention guideline for primary prevention. However, as the prevention guideline noted in the introduction, very limited and small-scale studies are available for clarifying the actual frequency of DVT in Japanese non-surgical patients. Since whether there is a benefit to prevent and treat hospitalized CHF patients for DVT has been unclear so far, we aimed to estimate the frequency of DVT in Japanese patients with CHF (NYHA III and IV).

Materials and methods

Before patient enrollment, the protocol had been evaluated and approved by the institutional review board (IRB) or ethical committee (EC) in each medical site. The investigator explained the purpose and methods of the study to the patients and then received his/her signed informed consent (IC) form before conducting any procedures of the study on each patient. The study was conducted by fully following the latest version of the Declaration of Helsinki (2008). The study was fully funded by a sponsor (GlaxoSmithKline, Japan).

This study is a multi-center, prospective, epidemiological study to estimate the frequency of DVT in hospitalized non-surgical Japanese patients with CHF.

Patients enrolled in the study were hospitalized patients identified as at high risk of VTE development based on a combination of risk factors in the prevention guideline. The inclusion criteria were patients with: (a) acute exacerbation of CHF (III or IV of NYHA classification of cardiac performance), (b) bed rest for 4 days and more, and (c) 60 years old or older. The exclusion criteria were patients with: (a) surgery or injury within 3 months before hospitalization, (b) diagnosed clinically or with obvious past history as having DVT at hospitalization, and (c) treated with any anticoagulants. When patients had any underlying diseases (valvular disorder, coronary artery disease, myocardial disorder, atrial fibrillation, atrioventricular block, hypertensive cardiovascular disease, and other diseases) and showed any symptoms related to heart pump dysfunction, they were diagnosed with congestive heart failure. We referred to Framingham criteria of the Framingham study [11] in the diagnosis. We evaluated the severity of heart failure by the NYHA functional classification, but did not investigate the detailed clinical conditions including central venous pressure, left ventricular dimension, left ventricular ejection fraction, and brain natriuretic peptide level in this study. We thus evaluated the occurrence of the DVT by the severity of CHF by using only NYHA classification.

After getting the IC from the patient, the presence of DVT was examined by using lower extremity ultrasonography (US) and the following data were collected.

Collected data

Collected data include demographic variables, life style variables, general medical history, physical examination, current medical condition, lower extremity vein US, and laboratory test (Table 1).

Diagnosis of DVT

Imaging techniques including US, venography, magnetic resonance venography, and contrast enhanced computed tomography have been used for the evaluation of DVT. Among them, diagnosis by US is non-invasive, and has been standardized in the guideline “Criteria for ultrasound diagnosis of deep venous thrombosis of lower extremities” [12] in 2008 by the Japan Society of Ultrasonics in Medicine. We thus considered that diagnosis with US is reproducible and reliable. The training meeting of diagnosis procedure for investigators and medical technologists was implemented before starting the study. The ultrasound diagnosis was performed between the 6th and 14th day of patient’s bed rest. If symptomatic

Table 1

Characteristics of patients with congestive heart failure (hospitalized).

Continuous parameters	N	Mean (SD)
Age ^a (years)	44	79.1 (10.6)
Body weight (kg)	44	53.3 (16.2)
BMI (kg/m ²)	44	22.5 (6.4)
Systolic blood pressure (mmHg)	44	124.8 (22.5)
Diastolic blood pressure (mmHg)	44	67.4 (16.7)
Duration of rest (days)	44	8.9 (5–16) ^b
Categorical parameters	N	%
Gender: male/female	19/25	43.2/56.8
Smoking history (male): yes (current or past)/no	9/10	47.4/52.6
Smoking history (female): yes (current or past)/no	2/23	8.0/92.0
Drinking habit (male): yes (current and past)/no	11/8	57.9/42.1
Drinking habit (female): yes (current and past)/no	1/24	4.0/96.0
Fitness habit (male): yes (current and past)/no	2/17	10.5/89.5
Fitness habit (female): yes (current and past)/no	8/17	32.0/68.0
Catheterization within last 3 months: yes/no	11/33	25.0/75.0
Basic disease	44	100.0
Valvular disorder	11	25.0
Coronary artery disease	9	20.5
Myocardial disorder	9	20.5
Atrial fibrillation	5	11.4
Atrioventricular block	4	9.1
Hypertensive cardiovascular disease	2	4.5
Other disease (including multiple diseases)	4	9.1
NYHA classification		
- The stages of heart failure	44	100.0
Class III (moderate)	14	31.8
Class IV (severe)	30	68.2
Physical prevention: yes/no	8/36	18.2/81.8
Medication of antiplatelet agents: yes/no	12/32	27.3/72.7
Medical history of VTE: yes/no	0/44	0.0/100.0
Concomitant disease of malignancy: yes/no	7/37	15.9/84.1
Concomitant disease of diabetes: yes/no	8/36	18.2/81.8
Concomitant disease of dyslipidemia: yes/no	11/33	25.0/75.0
Concomitant disease of hyperuricemia: yes/no	19/25	43.2/56.8
Concomitant disease of hypertension: yes/no	34/10	77.3/22.7
Concomitant disease of angina pectoris: yes/no	11/33	25.0/75.0
Concomitant disease of arrhythmia: yes/no	21/23	47.7/52.3
Concomitant disease of stroke: yes/no	7/37	15.9/84.1

BMI, body mass index; NYHA, New York Heart Association; VTE, venous thromboembolism.

^a Age: patient’s age at the time of ultrasonic examination.

^b Range (min–max).

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