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ORIGINAL STUDY

Parameters influencing thromboprophylaxis management of a lower leg trauma treated with a cast/splint

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Lower leg trauma is a frequent pathology in the emergency department of every hospital. Given the lack of a general consensus and the poor knowledge in the current use of pharmacological thromboprophylaxis, a cross-sectional, observational and epidemiological disease registry with 261 patients included by 16 centers was designed. These patients presented with a lower leg trauma and all needed a cast or splint to immobilize the injured leg. First, the different risk factors for thromboembolism and the type of injury in this population are mapped out. Secondly, the importance of both parameters in the decision making process to use or not to use prophylaxis in a lower leg trauma is discussed.

In the absence of clear guidelines, the presence of thromboembolic risk factors (type and number in a specific patient) and the type of injury are leading the decision to use thromboprophylaxis in emergency department of non-university hospitals, in patients with a lower leg trauma receiving a cast or splint to immobilize an injured leg.

Keywords : deep vein thrombosis ; pulmonary embolism ; leg ; trauma ; thromboprophylaxis ; risk factors.

INTRODUCTION

Lower leg trauma is a frequent pathology in the emergency department of every hospital.

Currently there are no good evidence-based data providing clinical guidance on venous thromboembolism (deep vein thrombosis (DVT) and pulmonary embolism (PE)) prophylaxis management in patients with lower leg trauma needing a cast *(3,4)*.

Although the epidemiology and prevention of venous tromboembolism (VTE) after lower extremity injuries have, unfortunately, been poorly studied, it is estimated that patients with below-knee injuries have a 10 to 40% risk of asymptomatic DVT *(4)*. Data from the few randomized trials with low-molecular-weight-heparins (LMWH) show that prophylaxis reduces the frequency of asymptomatic DVT, particularly in those with fractures or tendon ruptures *(4)*.

Although a substantial number of these patients are receiving pharmacological thromboprophylaxis in our practice because of a clear perceived risk for VTE, essentially by means of LMWH, minimal or no data exist on the level of risk associated with the type of lower leg trauma or the type of supportive

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physical therapy, the type and frequency of predisposing VTE-risk factors, and the decision making factors of thromboprophylaxis.

Given the lack of a general consensus and the poor knowledge in the current use of pharmacological thromboprophylaxis, a multicenter, cross-sectional, observational and epidemiological disease registry was designed. The main objective was to observe the physicians' attitude regarding the use or non-use of pharmacological thromboprophylaxis in patients with a lower leg trauma treated with a cast or a splint.

In this context the disease registry aimed to discern the parameters or combination of parameters that lead to the decision to use or not to use unfractionated heparin (UFH) or LMWH's for thromboprophylaxis (primary objective). The parameters included risk factors of thromboembolism and the type of isolated lower extremity injuries in each patient. In addition, the disease registry aimed to evaluate the link between these parameters and the decision to use thromboprophylaxis (secondary objective). Also the dosages and intended duration of treatment prophylaxis to be given were recorded.

PATIENTS AND METHODS

Between February and June 2006 (5 months), 261 patients were included from 16 centers (out of 19 contacted) all over the Belgian territory.

The inclusion criteria were : a) age $\geq$ 18 y, b) patient seen at first follow-up 'cast'-consultation for an acute lower leg trauma for which, about one week earlier (1-7 days after the trauma), initial treatment at the emergency department had been provided, c) written informed consent, d) lower leg trauma of foot, ankle or lower leg without need for surgical intervention, necessitating a physical support with a circular cast or splint for an additional 1-6 weeks after the study visit, e) ambulatory treatment of the lower leg trauma and f) normal mobility before the trauma.

Exclusion criteria were : a) need for hospitalisation at the moment of the lower leg trauma ($\geq$ 24 h in hospital), b) patient on anticoagulant treatment for any reason before the occurrence of the lower leg trauma, c) polytrauma patient, d) knee injury, e) pathological fractures (bone tumours, bone metastases, dystrophies or post-radiotherapy), f) surgical intervention within the preceding 4 weeks, g) patient participating in another study, h) estimated life-expectancy < 6 months as a consequence of the presence of a major invalidating disease, and i) impossibility to follow the guidance given by the treating physician.

Investigation was performed using a case report form (CRF) to be completed about one week after the acute trauma.

A predefined list of following VTE risk factors was used, essentially based on the ACCP 2004 risk factors *(4)*, although the CRF allowed for other factors seen as risk factors in the opinion of the investigators : personal history of DVT or PE, family history of documented DVT or PE, thrombophilia, other haemostasis disorders, immobilisation (e.g. > 4 days bed rest), age > 40 years, BMI > 30 (obesity), varices (gross varicose veins), hormonal replacement therapy (postmenopausal HRT), oral estro-(progestative) contraception, pregnancy or post-partum (< 6 weeks following delivery), cancer : active cancer and/or receiving anti-cancer therapy, heart failure : NYHA class III or IV, respiratory failure, active inflammatory disease like active inflammatory bowel disease and active rheumatoid arthritis.

As the ACCP and IUA recommendations do not make clear cut recommendations in this setting of isolated below knee/lower extremity injuries, it is not the intention to draw conclusions on which thromboprophylaxis management practices might be considered as appropriate or not, but to observe practices *(4,5)*.

The disease registry is observational and did not interfere with the normal clinical management of patients with lower leg trauma needing physical supportive therapy by means of a cast or a splint.

RESULTS

A total of 134 females and 119 males (missing data for 8 patients) were recruited. Ten centers out of 16 included 20 patients as planned.

The inclusion rate by centre is summarized in figure 1 (centers 4, 10 and 19 are not represented as they did not include patients).

The average weight, age and height were respectively 74.3 ± 13 kg, range 42 to 117 kg, 43 ± 17 years, range 11 to 86 years, and 1.71 m ± 0.09 (table I). Four patients were below 18 years of age, which were protocol violations. But as efficacy and safety were not objectives of this registry, these patients were included in the analysis.

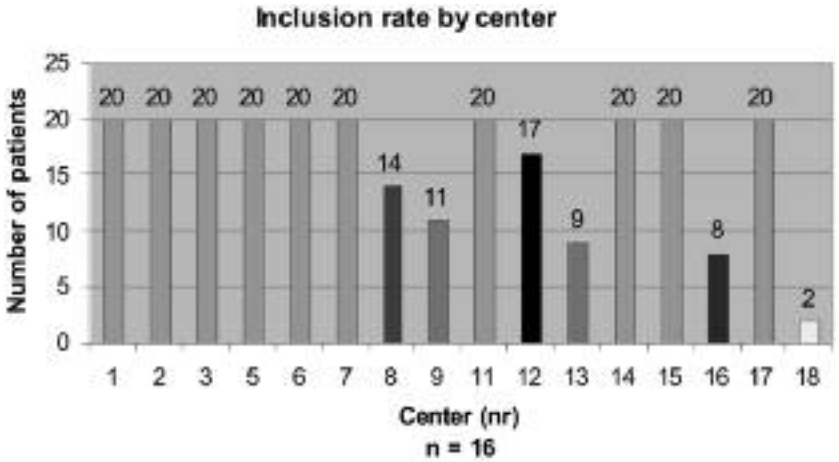

Fig. 1. — Inclusion rate by center

Table I. — Data on weight, height and age

	WEIGHT (kg)	HEIGHT (m)	AGE (y)
Average	74.3	1.71	43
Std Dev	13.2	0.09	16.9
Range (Min-Max)	42-117	1.50-1.94	11-86

The right lower limb was injured in 128 patients (49%), the left lower limb in 108 (41%), and the side was unknown in 25 (10%). A radiograph was taken in 240 patients (92%), no radiograph in 10 (4%) and this was not specified in 11 (4%).

The final diagnosis by side and with ratio fracture/ non-fracture was as followed :

- lower leg : 9 *(3%)*/9 *(3%)* ;
- foot : 60 *(23%)*/42 *(16%)* ;
- ankle : 35 *(13%)*/98 *(38%)* ;
- Achilles tendon rupture : 6 *(3%)*

About two thirds of the patients (67%) received a circular cast (versus splint) to immobilise the injured leg, for lower leg trauma including or not (about 60%) a fracture.

The types and frequencies of each identified risk factor are summarised in figure 2. Age > 40 years, gross varicose veins and immobilisation were the most frequent risk factors.

Patients had a mean of 1.7 ± 1.3 risk factors. Seventy eight percent of the study population had at least one underlying risk factor ; 26% had 2 risk factors, 18% had 3 risk factors and 9% had more than 3 risk factors (fig 3).

No single patient was documented to have thrombophilia.

A majority of patients (81%) in this setting were receiving prophylaxis. A total of 180 patients (69%) had ≥ 1 risk factor and were treated. Twenty-five patients (10%) had identified risk factors but were not treated. Conversely, 33 patients (13%) were treated while having no identified risk factors and 23 (9%) who had ≥ 1 risk factor were not treated.

Physicians indicated that their decision to prescribe prophylaxis was due to : 1) the presence of ≥ 1 risk factor (32%), the type of injury (21%), and for both reasons in 45% (fig 4).

A slightly higher proportion of patients with a fracture were treated (87%), compared with the proportion without fractures (78%).

All centers were using LMWHs, for an anticipated duration of therapy of 18 days (mean) ; more than one third of patients were going to be treated for 11 to 30 days, 20% for more than a month which corresponds to a need for a duration of therapy as long as the risk persists.

In 9 centers, all patients received prophylaxis, in 6 others at least half of the enrolled patients received prophylaxis. In one center, 3 patients out of 20 received prophylaxis.

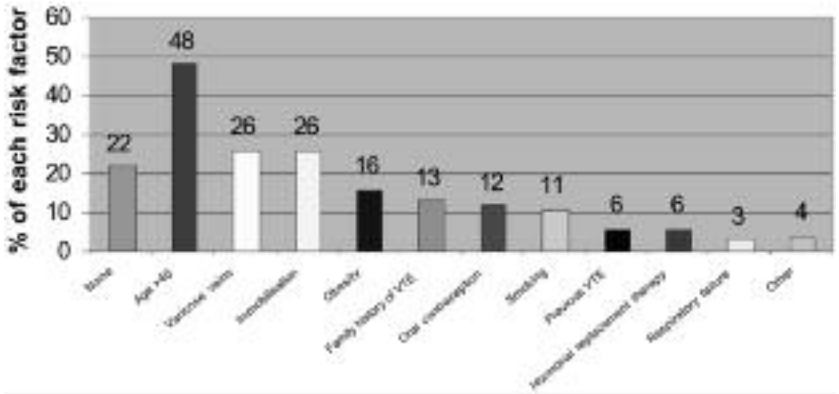

Fig. 2. — Types and frequencies of each identified risk factor

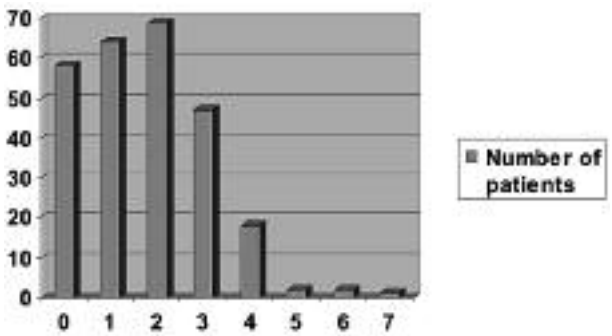

Fig. 3. — Number of risk factors per patient

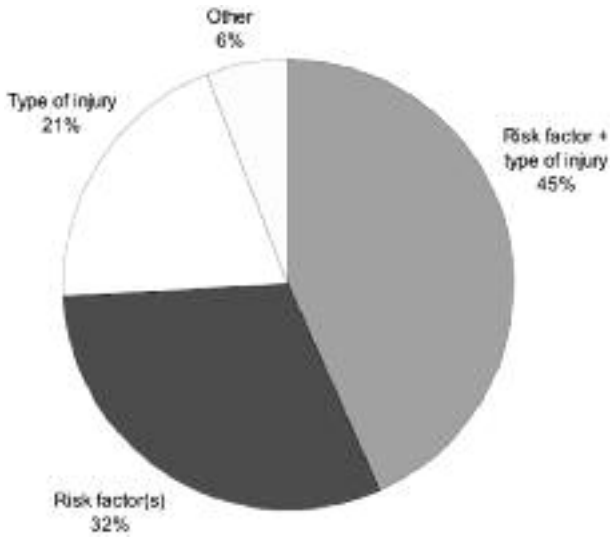

Fig. 4. — Reasons for giving prophylaxis

A majority of patients (n = 174) were receiving prophylaxis with enoxaparin 40 mg (78%) or nadroparin 0.4 ml (3%). A lower dosage of enoxaparin or nadroparin was used in 25 and 3 patients, respectively ; a dosage exceeding the prophylactic dosage was used in a very low number of patients (respectively 7 and 4 patients, for enoxaparin and nadroparin).

A delay of 2 ± 5 days was observed between the day of the trauma and the start of the prophylaxis.

DISCUSSION

A high prevalence of risk factors in this patient population with a plaster cast or splint for lower leg trauma was observed. With a mean of 1.7 ± 1.3 risk factors, the incidence of underlying VTE risk seems indeed to be significant. Age (older than 40 years), varicose veins, immobilisation, obesity, oral contraception, smoking, previous VTE, hormonal replacement therapy and respiratory failure were the most frequent risk factors.

In some references, age older than 40 years is considered as a risk factor by itself (*1*). Also varicose veins and immobilisation are considered as risk factors, albeit sometimes weakly associated (*1,2,4*).

Recently Riou *et al* emphasized in a study population of 2755 patients that a severe injury (mainly with an associated fracture), a rigid immobilisation,

and also lack of weight bearing appear as independent risk factors (*6*). The fact that no single patient was reported to have thrombophilia suggests a non-diagnosis in some patients, knowing that the prevalence in the general population varies from 0.03 and 15% depending on the type of thrombophilia (*5*).

The need for immobilisation and the impossibility to use mechanical methods in the prevention of DVT (elastic stockings or intermittent compression devices) in this setting makes the choice of prevention with LMWH obvious.

As many patients presented with several risk factors, one can consider them at increased risk for VTE, explaining the high prophylaxis rate in this study (81%). The proportion of patients (78%) with ≥ 1 or ≥ 2 (53%) underlying or transient VTE risk factors receiving prophylaxis is high. As the incidence of DVT in isolated lower limb injuries in the absence of prophylaxis is about 10 to 40% (*4*), and depends on the type and severity of the injury and of the presence of additional risk factors, which are likely to increase the risk of thromboembolism for individual patients (Consensus statement, International Angiology, 2006), it seems reasonable to consider both criteria, on an individual basis, when a decision is made for prophylaxis.

Indeed, the ACCP guidelines suggest that clinicians may choose to provide no prophylaxis, in-hospital prophylaxis or prophylaxis that is continued after discharge, and the IUA guidelines recommend to perform a thorough risk assessment and to use an approach using LMWH following a standardised protocol in an institution yet individualised for each patient.

In most of the patients (79%), the decision to treat or not to treat was made according to the presence or absence of risk factors. On the other hand, a minority of patients (21%) was treated while having no identified risk factors or were not treated while having ≥ 1 risk factor. About one in ten patients could have been treated due to the presence of one or more risk factors, a similar proportion was treated while having no identified risk factors. Thirty-three patients without significant risk factors for DVT were treated. One might consider that the type of injury played a major role in the decision to give prophylaxis.

Some variability in the proportion of patients treated with LMWH is observed between centers. A majority of centers were giving prophylaxis to most or all consecutively enrolled patients.

A majority of patients received prophylaxis with enoxaparin 40 mg, suggesting that this dosage was given to high-risk patients. Only 12% received enoxaparin 20 mg. The possible reason for this seems to be the lower risk in these patients given the lower dose. The presence of ≥ 1 risk factor and/or the type of injury guided the physicians' decision to prescribe prophylaxis, although this was not confirmed for the type of injury. Unfortunately no differentiated data were acquired for, respectively, the fractures and non-fractures and the injury side.

Patients were receiving prophylaxis for an anticipated duration of about 3 weeks, which is in line with the estimated persistence of the VTE risk.

This disease registry gives us valuable information about the prophylaxis prescription behaviour of the orthopaedic surgeon on the field in non-university hospitals, while data on this subject are lacking in the literature.

In the absence of clear guidelines, the presence of thromboembolic risk factors (type and number in a specific patient) and the type of injury are leading the decision to use thromboprophylaxis in emergency department of non-university hospitals, in patients with a lower leg trauma receiving a cast or splint to immobilize an injured leg.

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