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Venous Thromboembolism as a Preventable Patient Injury: Experience of the Danish Patient Insurance Association (1996 - 2010)

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1. Introduction

The mechanism of disease in venous thromboembolism (VTE) is mentioned, with emphasis on the rarer types of the disease. Next the conditions for approval of claims under the Danish Patient Insurance law are drawn up, and the typical situations for approval of VTE are listed. In the database of the DPIA we found 688 claims with this disease, and of these 421 were approved. The different types of VTE are examined, and the possibilities for prevention are discussed.

2. Of venous thromboembolism

Venous thrombosis is usually located in the veins of the lower extremity. The thrombosis probably has its origin in the valve pockets of the veins of the lower leg. There are several pathogenetic factors, but a common denominator is reduction of flow velocity in the veins. This may occur in a variety of situations, e.g.:

1. During anaesthesia it has been shown that the diameter of the veins increase, and thus the velocity of the flow decreases. At the same time the operative trauma increases the readiness of the thrombotic system.
2. In a number of different trauma situations to the leg, where immobilisation in casts or splints is used, rendering the venous muscle pump dysfunctionate,
3. In acute stroke, the afflicted leg is left without its normal venous muscle pump

These are classic examples of patients that may suffer a deep venous thrombosis (DVT) or more severely a pulmonary embolism (PE).

There are many clinical examples of variations on the theme.

The thrombosis may begin in the popliteal or femoral vein progressing centrally until it breaks off and sends its potentially fatal embolism to the lungs. It may also have its origin in the iliac veins, in which case the diameter of the ensuing embolism is sufficient large to close off the entire pulmonary artery, causing immediate death.

A special variety of the disease exists, where an obstruction is present at the iliac venous junction. This is called the *left iliac vein syndrome*, and it is normally not associated with pulmonary embolism, as the lumen of the left common vena iliaca is partially obstructed by a fine net of the endothelium at the junction. The compression from the crossing of the right common iliac artery adds to the obstruction.

In some cases the source of embolism is located in a venous malformation, and the thrombi to the lungs may be small and not easily clinically detectable. The pressure in the pulmonary artery increases slowly over months with the continuing pulmonal embolization causing cronical *cor pulmonale*. The *foramen ovale* may open under the increased pressure in the right side of the heart, releasing minor emboli to the arterial circulation. The end result is usually cardiac arrest due to the increased pressure with dilation of the right ventricle.

In rare cases the thrombosis occurs in the veins of the upper extremity. The size of emboli from the arms is not sufficient to give any serious problem from the lungs, but it is important to know that this possibility exists.

Thombosis in the mesenteric veins is a very rare, but potentially deadly disease. The onset of symptoms is much slower than that of arterial vascular ischaemia, where as a rule you have only 6 hours from the embolization to completion of thrombectomy, if gangrene and resection should be prevented. In venous ishaemia there are often days or weeks of symptoms before the onset of gangrene, and if the ischaemia has progressed to gangrene, a simple resection will often be sufficient. Venous intestinal ischaemia is usually not recognized until laparotomy, and it may be very difficult to make the diagnosis by laparoscopy alone.

Thrombosis in the venous sinuses of the brain is an important side effect to birth control drugs, and must always be considered as a differential diagnosis when a patient on the pill develops symptoms from the brain.

Finally, another inborn vascular anomaly has bearing on the embolisation from the veins of the lower limbs: The *foramen ovale*, which normally closes at the time of birth, will sometimes remain open and allow emboli from the right side to cross over to the left side and continue in the arterial system. This is known as "paradox" embolisation, and is important to consider, when a patient at risk for venous thrombosis suffers an arterial embolus. The frequency of patent *foramen ovale* in autopsy studies is about 20 %, so this a significant risk, as the frequency of deep venous thrombosis is equally high (1).

The disease known as thrombophlebitis, where a subcutaneous vein is inflamed and thrombosed, has nothing in common with DVT. In the major part of the 20th century it was thought that thrombosis might spread from the superficial veins to the femoral venous system through the sapheno-femoral junction, wherefore acute ligation of the junction was advised. This indication for the sapheno-femoral ligation has since been abandoned. Also, the practice of anticoagulation with thrombophlebitis is no longer advised.

3. The Danish patient insurance law

In Denmark, patients or relatives may file a claim if their medical treatment results in an injury or an unexpected side effect. The independent Danish Patient Insurance

Association (DPIA) will consider these claims. The DPIA operates on a no-blame, no-fault basis and does not take any legal action beyond assessing damages. As a result, patients may file a claim with the DPIA free of charge with the sole purpose of seeking financial compensation. Thus, the injured patient is spared the expense of legal fees and the trouble of going to court (2).

In general, financial compensation may be granted under any one of the following conditions:

1. an experienced specialist would have acted differently, whereby the injury would have been avoided,
2. defects in or failure of the technical equipment were of major concern with respect to the incident,
3. the injury could have been avoided by using alternative treatments, techniques or methods if these were considered to be equally safe and potentially offer the same benefits, and finally,
4. the injury is rare, serious, and more extensive than the patient should be expected to endure.

Compensation is calculated based on the extent of pain and suffering, reduced income, reduced ability to work, and medical expenses as well as whether the injury could be expected to be permanent. Compensation is rendered if the calculated amount exceeds 1,500 €. The government pays the compensations. After the decision has been made, the patient may file an appeal to the Patient Damage Appeal Board and further through the courts of law. From 1996 to 2010, the DPIA received 64,400 claims; 34.9 % of these were approved.

4. Venous thromboembolism and patient injury

VTE may be judged to be a patient injury in the following situations:

- when an injury was sustained, because the diagnosis of VTE was not made in a situation, where an experienced specialist would have done so,
- when VTE has been caused by giving a treatment without the proper prophylaxis,
- when a drug was prescribed that caused VTE,
- when the treatment of VTE was not up to the standard of the experienced specialist
- when the patient suffered more than he should be expected to bear considering his basic disease, the risk of treatment and whether the complication was rare and serious.

In such cases the DPIA may consider to give compensation if the other conditions of the law are met.

5. VTE and the database of the DPIA

Since 1996 we have maintained a database of all claims. Until the end of 2010, there were 688 claims, where the complication was VTE. In table 1 is shown the number of patients with DVT alone, the patients who also had PE, and the patients with rare thrombosis. The rates of approval of the claims are around 60 % compared to the average rate of 35 % of the DPIA.

Complication	N	N approved	Rate of approval
Deep venous thrombosis in the legs alone	390	226	58 %
Pulmonary embolism	266	176	66 %
Rare venous thrombosis	32	19	59 %
Total	688	421	61 %

Table 1. DVT and PE in the material.

There were 42 patients who died because of the patient injury (6.1 %).

The patients could be divided in 5 sub-categories after the nature of their disease and circumstances surrounding the injury (Table 2).

Invasive procedures	391
Birth control drugs	193
Other drugs	13
Non-operative fracture treatment	30
Missed diagnosis	15
Rare and miscellaneous	46
Total	688

Table 2. Categories of patients.

VTE after an open intervention was the largest group with 391 patients. The cause of injury was usually failing to give the correct prophylaxis, or omitting to give any prophylaxis at all. The specialities involved are seen in table 3.

Speciality	N invasive procedures	N approved
Orthopedic surgery	226	128
Surgery	94	52
Internal medicine	23	10
Gynaecology & Obstetrics	18	11
Neurosurgery	13	9
General practice	2	2
OtoRhinoLaryngology	5	5
Anaesthesia	3	2
Radiology	4	3
Neurology	1	1
Onchology	1	0
Dental surgery	1	1
Total	391	224

Table 3. The number of patients with VTE treated in the different specialities.

Of these, 27 patients died as result of the injury. There were 224 patients, who had their claims approved by the DPIA. Compensation was paid to 218 patients to the total amount of € 6.127.365.

6. VTE and treatment with female hormones

The other large group was 193 patients with DVT or PE, who had birth control medication (173 patients) or treatment of menopausal conditions (20 patients) prescribed by their physician, and suffered VTE as a result. Their claims were approved in 138 cases, and € 2.956.248 was paid to 134 patients. Only 5 women died, but it must be borne in mind that these were completely healthy women. In 17 cases it was later established that the patient had a coagulation defect, usually the Leiden factor-5 mutation.

There were at times several factors that contributed to the onset of thrombosis in these patients. Thus it was discussed which factor was the crucial one, when e.g. a young woman who was on birth control pills and had a body mass index of 34, undertook a long air travel and suffered VTE? The coagulation experts that we have consulted thought that the VTE would not have happened without the birth control medication, and that the contribution of the other factors was minor in comparison.

7. Treatment with other drugs

In 12 cases the VTE was thought to be caused by other drugs (Table 4). It was mainly claims with faulty use of anticoagulants that were approved. One patient died.

Other drugs	N	N approved
Vitamin K antagonist	5	3
Angiotensin converting enzyme	1	1
Immunoglobuline	2	1
Docetaxel	3	0
Cox-2 inhibitor	1	0
Prednisolone	1	0
	13	5

Table 4. The other drugs involved in VTE claims.

Non-operative treatment of fractures and joint injuries was the cause of 30 claims, shown in table 5.

Non-operative treatment of fractures and joint injuries	N	N approved
Spine	3	1
Lower extremity	27	13
	30	14

Table 5. VTE after non-operative treatment.

It was of course mainly fractures in the lower extremity that were afflicted because of the need for immobilization. Usually in the DPIA, VTE is thought to be a side effect of the fracture itself, and it is therefore not eligible for compensation. In 4 cases however, the diagnosis was missed, and in one further case the appeal board decided that the diagnosis should have been made at the time, when the cast was cut open because of swelling. In the last 9 approved cases there were individual indications for giving anticoagulants that were not recognized at the time of fracture. Four patients died as a result of the patient injury. In many of the non-approved cases, the question was whether the experienced specialist

would have used prophylaxis? For example, the recommended program for a non-displaced fracture of the tibia states that prophylaxis against VTE is not necessary; yet the frequency of DVT in these patients is 15 %. If we were to extend the program of prophylaxis to encompass ambulatory patients with a walking cast, these patients would only rarely suffer DVT, and some lives would be spared.

8. Missed diagnosis

In 15 cases without fractures or operation, the diagnosis of VTE was missed. The claim was approved in 12 cases (Table 6). These cases were evenly distributed among primary and secondary practice. Three patients died as result of the injury

	N	Approved
Hospitals	7	6
Primary sector	8	6
	15	12

Table 6. The number of missed or overlooked diagnosis of VTE.

9. Miscellaneous

The remaining 45 cases were a broad selection of the many different causes there may be for acquiring VTE, as well as a few that had a prophylaxis or a treatment of VTE that wasn't up to the standard of the experienced specialist (Table 7).

Rare or miscellaneous	N	N approved
Upper extremity	20	10
Sinus thrombosis	11	9
Venous puncture or catheterization	4	4
Wrong prophylaxis or treatment	4	4
VTE i spite of correct treatment	3	0
Mesenteric venous thrombosis	2	1
Paradox embolism	1	1
	45	29

Table 7. Rare or miscelleaneous patients.

The cases of cerebral sinus thrombosis were all caused by birth control medication. Three of the cases of venous puncture were caused by blood donation; such claims are nearly always approved by the DPIA. Two of the 45 patients died.

There were 83 claims that went on to the appeal board, and of these 15 had the decision of the DPIA altered. The changes of decisions nearly all concerned the size of the compensation. One claim went on to the high court. It concerned a male of 33 years, who had a percutaneous endoscopic ligature of the spermatic veins for a *hydrocele testis*. Afterwards he suffered a hemorrhage in the scrotal sac and a venous thrombosis in the leg. The compensation in the DPIA was € 95.165, and this decision was upheld both before the appeal board and in the high court.

10. Discussion

The standard prophylaxis in Denmark is usually given only for the duration of admittance to hospital, or until the patient is well mobilized. During recent times, a number of studies have suggested that this is not enough, and that prophylaxis should be given for 6 or 8 weeks after surgery (3, 4). The price would be manageable, and the logistics could probably be overcome. Why do we accept that hundreds and hundreds of patients go without prophylaxis for the period they are at risk?

Also, it is not rare to see a patient described as "well mobilized" and therefore have his prophylaxis discontinued, when in fact he is only out of bed for a few hours a day and then only sitting in a chair. The sitting position, if anything, increases the stasis of blood in the veins of the legs, and therefore probably also increases the risk of VTE. The development of tablets for VTE prophylaxis may change this state of affairs in the future, since it will make the administration of medication simpler (5, 6).

The treatment of VTE goes hand in hand with the prevention of the disease. When you have seen the damage that VTE can do to patients, you are likely to go far to prevent a single case. There exists well-proven mechanical as well as biochemical methods with very few side effects. All of these 688 cases must be viewed as potentially preventable with the exception of the 3 cases, where VTE occurred in spite of the fact that correct prophylaxis was given. Of course it is not possible to prevent all cases, which you can see by the fact that these 3 cases occurred. But this must not be given as an excuse to omit prophylaxis.

It is inexcusable to perform major invasive treatment without prophylaxis, and probably the medical profession should consider extending the indications as well as the duration of prophylaxis. The cost of doing this will be balanced against the gain from not having to treat the VTE-cases and the tax returns from the survivors of complications to VTE (7).

It should probably also be considered to screen the women for coagulation deficits before they are placed on contraceptive medication. Certainly, it is clear from our records, that the medical profession should consider the differential diagnosis of VTE in patients on contraceptive drugs more often.

For the DPIA it is also a question whether you should approve claims from women, who have a coagulation defect like Leiden factor-5 mutation? There were only 17 cases where our patients had been tested positive for this genetic defect. The true number is probably much higher. Normally, the DPIA does not approve claims, when a patient has a disposition to the injury. It can be argued, however, that the experienced specialist would not prescribe contraceptive drugs to a patient with Leiden-5 mutation. It is therefore the normal practice of the DPIA to approve these claims.

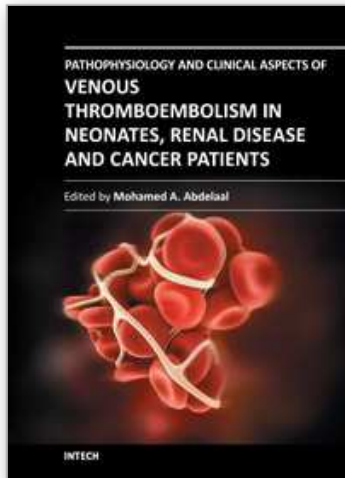
The fractures that are treated by non-invasive means are by no means immune from VTE. A recent metaanalysis of the question of prophylaxis to these patients (8) states that ambulatory patients with temporary lower leg immobilization who are over 50, in a rigid cast, non-weight bearing or with a severe injury should be considered as a risk group for VTE. The present opinion is however, that the VTE in these cases is caused by the trauma and not the treatment. The patient that dies from PE probably doesn't care. We think that it should be seriously considered to include these patients in an anti-VTE program.

We realize that there are many claims that never comes to the knowledge of the DPIA. The reasons for this are many: Ignorance of the law, resignation in the face of a serious disease complicated by the injury, the bother of the application procedure, fear of alienating the physician etc. We have tried several methods in order to achieve a more precise estimate of this problem (9, 10). Our best estimate is now that there are at least 4 – 5 patient injuries for each claim.

The risk of VTE increases with malignancy, infections, reoperations and surgery close to the large veins. The prophylaxis should be adjusted accordingly. It is about time that the medical profession starts to realize that posttraumatic or postoperative VTE is not an inevitable event. It may be prevented by a number of quite effective measures, but a change in attitude from the medical profession is required.

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