



HANDLING DEEP VEIN THROMBOSIS AND PULMONARY EMBOLI CASES

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Attorneys who handle medical negligence claims are likely to encounter claims involving deep vein thrombosis (DVT) and its sequelae, post-thrombotic syndrome and pulmonary emboli (PE). DVT occurs when a clot or thrombus forms in the deep veins (usually of the leg or pelvis). If the thrombus, or a piece, breaks free it can be carried through the vessels and the heart until it gets to a point where the vessel is too narrow, in the pulmonary artery. The clot (called an embolus once it breaks free) can then completely block the vessel and prevent blood from moving past it to the lung (called a pulmonary embolism). This can result in death or in serious damage to the lungs. In fact, deaths from PE are the leading form of accidental death for hospitalized patients, and the second most common cause of unexpected death in the general population, with over 200,000 deaths per year in the U.S. It has been estimated that one in twenty people develop DVT during their lifetime, and 60,000 hospitalizations for DVT occur annually in the U.S.

DEEP VEIN THROMBOSIS

Even if a PE does not result from an episode of DVT, in the absence of treatment with an anti-clotting drug, the thrombus will usually extend or propagate, obstructing even more of

the veins in the leg. As it does, the body has a natural tendency to lyse or break up the clots, and in time "re-canalization" of the veins occur. This process can result in damage to the valves in the leg veins. If valvular damage is widespread or severe, it can result in post-thrombotic syndrome (chronic venous insufficiency), a condition in which the blood continually pools in the leg because of valve incompetency, causing swelling, pain, and skin ulcerations.

In its severe forms, post-thrombotic syndrome can be disabling, not only because of the skin ulcers but because the individual must spend many hours each day with the leg elevated above the level of the heart to alleviate the swelling and the pain. In rare cases the swelling can cause an increase in compartment pressures, leading to venous gangrene and amputation.

The causes of DVT are varied and not well-understood. In general, it is thought that a clot occurs when there is a combination of venous stasis (pooling of the blood), a pre-existing hypercoagulable state or condition (a clotting disorder in which the blood clots easily), or some form of abnormality or injury to the vessel wall. Venous stasis can occur during extended bed rest (thus explaining the risk to hospitalized patients) or because of inactivity after orthopedic or other surgeries. Hypercoagulable states are varied and can be associated with inherited disorders as well as acquired conditions.

Injury to the vessel wall is less well understood, and may not be present at all, but when it occurs it can cause an irregular surface that facilitates clot formation. Vascular injury can occur from IV catheters, infection, surgery, and a variety of other causes.

Many risk factors for DVT have been identified in the medical literature, and even quantified for diagnostic purposes. In general, age, immobilization for more than three days, major surgery, or even long airplane trips can be associated with venous stasis and an increased risk of DVT. Pregnancy and the post-partum period increase the risks, as do some birth control pills or hormone-replacement medications. Many medical conditions can predispose a patient to DVT, including cancer, previous episodes of DVT, and an acute myocardial infarction.

Pre-existing clotting disorders, such as protein C deficiency, protein S deficiency, factor V Leiden, and other inherited disorders, increase the risk of DVT. Even when a patient's risk factors are known to the physician, however, the symptoms of DVT can be so varied and non-specific that diagnosis is often impossible without a thorough physical examination and appropriate diagnostic testing.

The most common symptoms of lower extremity DVT are swelling and pain, and sometimes skin discoloration. Occasionally the patient will also have a low-grade fever. If those symptoms are

present in a patient who has been bedridden or convalescing from surgery, or who has been non-ambulatory for some other reason, or who has other substantial risk factors for DVT, then the diagnosis of DVT must be considered and ruled out. However, in many cases DVT is clinically silent, and the condition may be diagnosed only after there has been a death from pulmonary embolism and an autopsy reveals clots in the legs or pelvic vessels.

Diagnostic testing for DVT includes a through physical exam, and a Doppler ultrasound, in which sound waves are used to estimate blood flow through the veins. By pressing an ultrasound probe against a vein, the ultrasound technician can determine whether or not the vein is “compressible.” If not, then a clot is suspected to be partially or completely occluding that segment of vein. The gold-standard test is a venogram, which involves injection of dye that can be seen on fluoroscopy (x-ray). An MRI can also disclose the existence of DVT, although its use is not yet widespread for that purpose. Most claims involving a delay in diagnosis of DVT involve the failure of a physician to perform a timely, thorough physical examination and order a Doppler scan in the presence of clinical symptoms and risk factors for DVT.

Treatment of DVT involves anti-coagulant medications, usually heparin and Coumadin, to prevent extension or propagation of the clots, and to avoid pulmonary embolism. Heparin is usually given IV in the hospital, and then oral Coumadin is started and continued after the patient achieves an adequate level of anticoagulation (blood thinning). In some hospitals, DVT is treated with tissue-plasminogen

activator (tPA, sometimes called a “clot-buster”) to try to lyse existing clots, but tPA is not yet a generally accepted standard of treatment for DVT.

It had been thought that giving Coumadin for a few months was adequate to prevent DVT recurrence, but the current thinking is that the risk of recurrent DVT continues for at least six months, and Coumadin should be administered for at least that long. If there is a recurrence of DVT, the risk of developing post-thrombotic syndrome increases sharply. In cases where a patient has a coagulation disorder, Coumadin may be given on a life-long basis in order to avoid recurrence.

Once heparin treatment is started, the clots stabilize and the risk of dislodging and developing a pulmonary embolus decrease. The body begins the process of dissolving the clots through a natural process of lysis. If the clots are primarily in the calf veins, they will often dissolve without treatment, and with little long-term effect. However, if the clots form in the thigh or pelvis (such as the iliofemoral veins), they are often larger and will frequently affect the veins further down in the leg. Almost 90% of patients with a large DVT in the thigh or pelvis will suffer some degree of valve damage, although the degree of disability may vary greatly depending on the extent of the occlusion, the veins occluded, and the length of time the condition has remained untreated.

PULMONARY EMBOLISM

If a DVT dislodges and travels through the vessels and heart, it will stop at a point where the vessel is too narrow for the clot to go any further; usually in the pulmonary artery or one of its branches. This results in partial or

complete obstruction of blood flow to one or both lungs. Occlusion of the pulmonary artery causes a section of lung to be ventilated (supplied with air), but not perfused (supplied with blood). This leads to acute respiratory distress and heart failure or cardiogenic shock, and death can occur within minutes.

If smaller clots lodge in a branch of the pulmonary artery, there may be few symptoms other than increased heart rate or shortness of breath. Repeated episodes of smaller PE over time, however, can cause pulmonary hypertension, right heart failure, and death. If the smaller PE are diagnosed and treated in time, further DVT propagation and embolization, and more serious injury or death, may be prevented.

The symptoms of PE, like those of DVT, can be silent, but in many cases they consist of one or more of the following: sudden cough (or coughing up blood, called hemoptysis), acute onset of shortness of breath, lightheadedness, fainting or dizziness, chest pain that increases when inhaling, sweating, anxiety, tachypnea (rapid breathing), or tachycardia (rapid heart rate). All of these symptoms are non-specific, i.e., they are consistent with conditions other than PE. Thus, specific diagnostic tests are necessary to rule out PE. The three most common tests are pulmonary angiography, nuclear lung scan (VQ scan), or spiral CT scans (which involve iodine dye injected into a vein while the patient is scanned in a spiral CT scanner). The VQ scan is the most common test for PE, but the spiral CT scan is becoming increasingly popular as a diagnostic tool.

The treatment for PE is the same as for DVT: anticoagulants (heparin and Coumadin) and possibly thrombolysis



(use of clot-busting drugs). To prevent recurrent DVT that could lead to PE, the patient may also use graded elastic stockings. In some cases, a Greenfield filter (a filter placed in the vena cava to trap clots that break off from DVT) may be installed to prevent clots in the pelvis or leg from traveling to the lungs.

Without effective treatment, the rate of recurrence of DVT and PE may be as high as 50%, and PE mortality may reach 30%. The risk of death increases with each recurrent episode of PE. With timely diagnosis and treatment, the rate of recurrence and mortality is significantly reduced.

PREVENTION

Inpatients who undergo surgery and who have risk factors for DVT, several prophylactic therapies may be utilized. Complex “scoring” systems have been developed in which numerical values are assigned for various risk factors, such as age or medical conditions, and this determines whether prophylactic drugs should be used during or after surgery. Prophylactic medications such as heparin or Coumadin can markedly reduce the incidence of DVT, but they also involve an increased risk of bleeding and may not be appropriate for some surgeries. Pneumatic compression stockings, such as Flowtron stockings, may be used during surgery and the post-operative periods, and are removed when the patient is fully ambulatory. Leg and calf muscle exercises and graduated compression stockings (TED hose) are also used for DVT prophylaxis.

MEDICAL NEGLIGENCE CLAIMS INVOLVING DVT AND PE

An attorney may encounter potential claims involving DVT and PE in many

and varied settings. A typical case will involve a patient who has undergone orthopedic or other surgery requiring immobilization for a few days to a week, and who presents to his physician or the emergency room several days later, with symptoms such as leg swelling or acute leg pain. In those cases, the examining physician must include DVT in the differential diagnosis.

A traditional examination for DVT is to test for “Homan’s sign”: pain in the calf muscles upon forced dorsiflexion of the foot with the knee straight. This test is not very sensitive, since it can be positive in patients without DVT and negative in patients with DVT. If there is a clinical suspicion of DVT, duplex ultrasound scanning is the most frequently utilized diagnostic test. Ultrasound is non-invasive, painless, and inexpensive, and will diagnose most DVTs located in veins above the knee. For diagnosis of calf DVT, venography may be required.

As noted earlier, most claims of failure to diagnose DVT involve analysis of the clinical symptoms and risk factors in the context of the physician’s failure to perform an adequate physical examination and to order diagnostic testing for DVT.

If the patient presents with signs or symptoms of PE – whether or not there are symptoms of DVT – a prompt referral for appropriate diagnostic tests may prevent death or serious damage to the heart and lungs. Any combination of shortness of breath, chest pain upon inhaling, or dizziness, if present in a patient who has other risk factors for DVT, must include PE in the differential diagnosis and the physician should rule out PE.

A thorough history is important; if the physician doesn’t know that the patient had a recent leg injury or doesn’t elicit a history of prior DVT or a family history of coagulation problems, non-specific symptoms may result in inadequate diagnostic testing and discharging the patient with a presumptive diagnosis of anxiety or stress.

Another context in which DVT and PE medical negligence claims arise is in the days following a surgical procedure. When evaluating the claim, the attorney must ask whether the physician took reasonable prophylactic steps to prevent DVT formation, such as use of pneumatic stockings or compression stockings during the post-operative period. In a patient with substantial risk factors for DVT, did the physician consider the use of low-molecular heparin or Coumadin? Are orders given for the nurses to perform leg exercises or to have the patient out of bed and ambulating as soon as possible?

Recently, there have been a number of reported cases of death from PE in patients who had surgeries – usually cosmetic plastic surgery – in office operating suites, and who were then sent home or to a hotel following minimal post-operative recovery time. Some plastic surgeons perform lengthy and complex surgeries in office suites, without adequate consideration of risk factors for DVT and without appropriate prophylaxis for DVT. Lengthy procedures, under general anesthesia, can lead to venous stasis and increase the risk of DVT development.

As a result of reports of post-operative deaths from PE, some states, including Florida and New York, are considering legislation to limit the length of surgeries that can be per-

formed in office surgical suites. A surgeon must assess the risks of DVT and PE, and ensure that adequate prophylactic steps are taken and appropriate post-operative care given. If not, a claim of medical negligence may arise if the patient suffers a DVT or PE.

HANDLING DVT AND PE CLAIMS

If you encounter a potential claim involving DVT or PE, obviously the right experts are needed. A claim involving a failure or delay in diagnosing DVT requires an expert in the same medical specialty as the potential defendant (general surgery, orthopedics, emergency medicine, etc.). A vascular surgery expert is needed to explain the pathophysiology of thrombus formation, and the effect of thrombus on venous “one-way” valves. Other sequelae of DVT that are best described by a vascular surgeon include lower extremity valvular destruction and vein re-canalization, the development and sequelae of post-thrombotic syndrome, and the process of clot embolization.

Some internal medicine specialists, especially in academic medicine, also have particular expertise and background in DVT and PE. A pulmonary medicine specialist may be required to explain the effects of pulmonary embolus on blood flow through the heart and lungs, and the pathophysiology of dead space ventilation-perfusion defects and right ventricular failure. There is ample information on DVT and PE available on the internet, but prior to an internet search you should consult a standard internal medicine reference text for general information. More detailed information on the pathophysiology of DVT can also be found in vascular surgery texts, and

information regarding PE can be found in standard pulmonary texts.

The defense of DVT and PE cases can be expected to raise the following issues regarding negligence: DVT is often difficult to diagnose and may mimic other conditions; pelvic DVT’s are often asymptomatic and present as PE or sudden death; and DVT prophylaxis (anticoagulation) is associated with increased risk of bleeding, and may be contraindicated in some patients.

The emphasis for the plaintiff’s attorney in establishing negligence in failing to diagnose DVT is to assess the symptoms that were present, along with the risk factors. If a physician should have known of such symptoms and risk factors, it is incumbent on the physician to explain why he/she did not consider DVT or PE and did not perform an appropriate examination or order diagnostic tests. The morbidity and mortality associated with DVT and PE are so great that it is not “reasonable and prudent” to brush aside symptoms or to attribute them to a less serious cause without adequate diagnostic tests. Until DVT or PE can be ruled out, the risks to the patient are too great.

A meticulous review of the medical record is needed. It is not uncommon in an emergency room case to find that the ER physician’s note or report cites only a few symptoms. The triage nurses’ note, however, will often include a longer list of presenting symptoms. If the nurse notes “shortness of breath,” but the physician does not note it, then the failure of the physician to elicit this symptom, or failure to recognize its significance, may be the primary basis for a claim.

As in other claims involving a failure or a delay in diagnosis of a medical condition, issues of causation will often loom large. Patients often don’t recognize the symptoms of DVT, and that can result in delay in presenting for treatment. The contention will be that the damage was already done by the time the physician could have diagnosed DVT or PE. The amount of valvular damage from DVT is also difficult to predict based on the extent of clots, and may occur early in the disease process if critical valves, such as those in the iliofemoral veins, are involved with clot.

Most physicians would agree with the proposition that “the earlier the treatment, the better the result,” but the burden will be on the plaintiff to establish that diagnosis and treatment at a particular time would have prevented the valve damage and consequent post-thrombotic syndrome. The more serious the symptoms at presentation, the stronger the negligence claim; but the seriousness of the symptoms may also mean that causation is more difficult to prove. Claims involving failure in preventing or diagnosing DVT or PE often become the classic “battle of the experts,” both with regard to negligence and causation. To prevail, an attorney must have a good grasp of the medical facts and theories and be able to present them through credible and articulate experts.

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