



## PULMONARY EMBOLISM: INADEQUATE PROPHYLAXIS LEADS TO CLAIMS

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The American public is generally unaware of a major health care crisis that kills 60,000 to 200,000 Americans each year. The tragedy is that many of these deaths are preventable. For each victim the tragedy begins when a blood clot that has formed in the large interior veins of the leg (deep vein thrombosis or DVT) breaks loose and enters the blood stream (where it is called an embolus).

When the embolus lodges in the lungs and cuts off oxygen to the lungs, it is called a pulmonary embolism (PE) and it is often fatal. As many as 600,000 people in this country develop pulmonary embolism annually; those who survive often suffer long-term complications and require years of treatment. The majority of these incidents occur while the victim is hospitalized for unrelated reasons and, in fact, occur as a consequence of surgery or the hospitalization itself. Not surprisingly, many in the medical community think that the incidence of deep vein thrombosis (DVT) and pulmonary embolism (PE) in the hospital setting is a serious health crisis.

In March, 2003, the Centers for Disease Control and Prevention, with the American Public Health Association, sponsored a national conference to discuss better means of preventing deaths from DVT/PE. A Harvard Medical School professor said at the time that the statistics on DVT/PE are “quite shocking”

and that “there are so many preventable deaths” that it has become a crisis. The published statistics are estimates, because autopsies were often not performed to determine whether blood clots were the cause of death.

This means that there are many potential cases where one may be able to establish that reasonable and prudent prophylactic care was not given and the patient suffered injuries and, in many cases, death as a result. These are often classic cases of “the surgery was a success but the patient died.” The kinds of prophylaxis, which will be discussed in more detail later in this article, include sequential compression stockings and various forms of low-dose Heparin (a blood-thinning medication).

In a Trial News article in May, 2000, I described the pathophysiology of DVT and PE, and noted the importance of appropriate prophylactic measures for surgical patients who are at risk for developing these conditions. I won't repeat the detailed explanation in that article of how DVT develops and can lead to PE. In summary, surgical patients who are not ambulatory for several days post-op and have other risk factors can develop clots in their legs that can result in small pieces (emboli) breaking off and traveling to the lungs. When that occurs, the patient can suffer serious pulmonary symptoms and cardiac arrest.

Actual practice seems to be lagging behind current medical thought and literature regarding prophylaxis for DVT/PE, as shown by the many publications urging providers to take action to prevent DVT/PE. Many physicians (especially surgeons who focus more on the surgery and less on post-operative care) do not give sufficient thought to the risks of DVT/PE in their patients. Consequently they often fail to consider what prophylactic measures might be appropriate or to order them. Many patients thus do not receive appropriate prophylaxis. One estimate is that only 1/3 of patients who are at risk receive even minimal prophylaxis.

In 1998, the University of Massachusetts Medical School published “Best Practices: Preventing Deep Vein Thrombosis and Pulmonary Embolism.” In that publication, they emphasized that simple, cost-effective means can be used to avoid many if not most of these potentially deadly complications. A premise of the article is that the major problem in implementing effective prophylaxis in the hospital setting is lack of knowledge on the part of physicians and hospital staff that such treatment is both needed and effective. Since then, there have been many warnings and publications about the need for DVT/PE prophylaxis in hospitals, but the high complication and death rates appear to continue. A few hospitals are now developing formal protocols for prophylaxis to

prevent DVT/PE, especially in high-risk patients, but most leave these decisions to individual physicians.

Patients who are at risk for DVT and PE include those with:

1. *Certain medical conditions (such as chronic obstructive pulmonary disease or pneumonia)*
2. *Cancer after chemotherapy*
3. *Major surgeries (particularly orthopedic surgery)*
4. *Inherited coagulopathies (tendencies toward clotting)*
5. *Other risk factors (such as increased age, obesity, pregnancy, or use of birth control pills)*

Although there is a consensus that some surgeries, particularly hip and knee replacement surgery, almost always require some form of prophylaxis for DVT, there is less agreement about other surgeries. In general, the more risk factors that are present for a surgical patient, the greater the need for ordering DVT prophylaxis.

## WHAT PATIENTS ARE AT RISK AND REQUIRE PROPHYLAXIS

The latest monograph on prevention of DVT/PE from the American College of Chest Physicians, published in 2001, contains a complex “risk factor stratification.” The analysis outlines “low risk” to “highest risk” patients in terms of the type of surgery to be performed and the presence of other risk factors. For example, minor surgery on a patient under the age of 40 with no additional risk factors places the patient in a low risk category in terms of statistical likelihood of developing DVT or PE after surgery. A moderate risk patient includes those having minor surgery but being over age 40 and with some

additional risk factors, and the highest risk patients would be those having major surgery, plus are over age 40, had prior DVT, cancer, or a hypercoagulable state, or had hip or knee surgery or major trauma or spinal cord injury.

Most patients with DVT do not go on to develop symptomatic PE, but the presence of DVT is a necessary prerequisite for PE. Because of the difficulty in diagnosing PE when it occurs (it can often be “silent”) and the speed with which PE can result in death, the goal is to prevent DVT in the first place. Screening tests for DVT, such as impedance plethysmography and duplex ultrasound, are not predictive for DVT in patients without symptoms. Even if PE does not develop, undiagnosed and untreated DVT can result in a disabling post-thrombotic syndrome, as well as a predisposition to future episodes of recurrent DVT.

The list of clinical risk factors for DVT is a long one, but is worth including in this article because their presence or absence may help determine whether a reasonable and prudent physician should have ordered prophylaxis in the hospital setting:

- *Increasing age (starting with age 40)*
- *Prolonged immobility (whether from surgery or otherwise)*
- *Stroke or paralysis*
- *Previous DVT episode*
- *Cancer with chemotherapy*
- *Major surgery (abdomen, pelvis and legs)*
- *Trauma (especially to pelvis, hip, or legs)*
- *Obesity*
- *Varicose veins*

- *Cardiac dysfunction*
- *Indwelling central venous catheter*
- *Inflammatory bowel disease*
- *Pregnancy or estrogen use*

Another major risk factor is a pre-existing tendency to excessive clotting (coagulopathy) or a family history of DVT. Some people who develop DVT after surgery may do so in part because of an undiscovered coagulopathy. There are many thrombophilic abnormalities, and more are being discovered each year. The most common are activated protein C resistance (factor V Leiden), antiphospholipid antibodies (such as in lupus patients), protein C or protein S factor, and prothrombin variant 20210A. If it was known that a patient had any of these factors, the case for DVT prophylaxis after surgery or immobilization because of trauma would be much stronger. Unfortunately, few patients know they have these factors before they develop DVT, and routine pre-surgical blood testing usually does not screen for these conditions.

Despite published statistical risk stratifications, the Chest publication cautions that “prophylaxis decisions for an individual patient are best made by combining knowledge of the literature... with clinical judgment...” This caveat, of course, is what makes this issue less clear in terms of proving medical negligence in any particular case, and allows the classic “judgment call” defense to be raised. As in all medical negligence cases, the proof will be provided through expert medical testimony, and a failure to use prophylaxis for patients who are higher in the risk stratification will provide a stronger



basis for the expert's opinion that the care provided was not reasonable and prudent.

The strongest cases will be those involving orthopedic surgery of the hip and legs. The Chest monograph noted above contains the following statement:

*"Clinical trials and cohort studies have provided a clearer picture of the natural history of VTE [DVT/PE] associated with major orthopedic surgery of the lower extremity and have also provided considerable information to guide decisions about prophylaxis. Based on the results of contrast venography... the prevalence of DVT at 7 to 14 days after total hip replacement, total knee replacement and hip fracture surgery is about 50-60% with proximal DVT rates of about 25%, 15 to 20%, and 30% respectively."*

In most cases, the clots in the leg resolve spontaneously through a natural lysing process, but in a few individuals the clots will propagate and result eventually in pieces breaking off and becoming PE. Why this happens is unclear, but may result from a venous injury, an inherited coagulopathy, stasis due to prolonged immobility, or some as yet unidentified factor.

DVT can develop as late as 14 days after orthopedic surgery (studies show that 45-80% occur after discharge) and this means many patients will be out of the hospital and at home when the clots occur. The orthopedic surgeon thus must "manage" the patient's DVT prophylaxis when the patient is no longer in the hospital. In practice, orthopedic surgeons and their office staff may not be well-prepared to supervise out-patient care of this kind. Someone

has to prescribe post-operative coumadin (warfarin) to prevent clots and also arrange for periodic outpatient blood tests to measure therapeutic levels so that adjustments can be made in the medication to achieve maximum therapy with minimum risks of bleeding.

A fairly recent development in some hospitals is to have a facility which takes over the testing and medical adjustment function for patients who are discharged from the hospital to ensure that DVT or PE does not occur. In many hospital settings, however, it is the surgeon (or sometimes the primary care physician) who will have that responsibility.

The most common defenses to a claim of negligent failure to use prophylaxis for DVT are that the risk factors were not significant enough to warrant it or that the risk of bleeding outweighed the benefits of prophylaxis. Studies, however, have shown that bleeding complications are quite low with use of low-dose or low-molecular weight heparin. Mechanical prophylaxis (such as sequential compression stockings) of course carry no risk of bleeding and, in some patients, have been shown to be efficacious. The various means of prophylaxis are outlined below.

#### METHODS OF PROPHYLAXIS

Prophylaxis can be either pharmacological or mechanical. The latter include sequential compression stockings and foot pump mechanical devices. These devices act to compress leg muscles and force blood back up through the veins, thus preventing the stasis that is thought to be a common predictor for DVT. Although the studies are not entirely clear as to the efficacy of mechanical devices, some

have indicated that they are effective in reducing distal (calf) DVT by more than one-half. They do not prevent proximal (iliofemoral vein) clots. Since the calf clots appear to be most common, in general the use of mechanical devices is seen as an effective means of preventing many DVT/PE cases. Some studies have shown that their use in conjunction with antithrombolytic drugs is more effective than either prophylactic method alone.

Of the pharmacologic prophylaxis, two are most commonly used: low-dose unfractionated heparin and low-molecular-weight heparin. These are given intravenously (IV). There are numerous studies showing the efficacy of both drugs in various kinds of surgical settings. For general surgery patients, one meta-study showed a more than three-fold reduction, from 0.7% to 0.2%. For orthopedic surgeries involving the hips and legs, where the incidence of DVT/PE is much greater, the effectiveness is more striking. Although aspirin is an anticoagulant, and is sometimes used to prevent DVT/PE, the studies do not show that it is effective for that purpose.

Which heparin to use is somewhat controversial and studies show differing results. One contraindication to low-molecular-weight heparin is a study showing that in patients with spinal or epidural anesthesia, paralysis may develop in rare cases. Studies have shown that both drugs are equally efficacious for general surgery patients, but there are differing conclusions for gynecological, neurological, and orthopedic surgeries. The use of which drug for what surgery and under what circumstance is complex and beyond the scope of this article. The best analysis

can be found in the Chest monograph, and in the article by Kaboli, et al., published in the Medical Clinics of North America in January, 2003 (see the references cited at the end of this article).

The timing and sequence of prophylaxis varies. Some physicians routinely use sequential compression stockings during surgery and keep them on during the post-op period until the patient is completely ambulatory. Heparin may be started either before the surgery, during surgery, or immediately following the procedure. Studies have been unclear as to which is most effective. If it is intended to use coumadin (warfarin) as an oral anticoagulant after hospital discharge, some patients will be started on low-dose coumadin at the same time heparin is started, and then the IV heparin is stopped and the oral coumadin dose increased at the time of discharge.

Coumadin is not used as an immediate post-surgical prophylaxis because its onset of action is delayed and, unlike heparin, its effects cannot be quickly reversed. It usually takes three days to become effective. When it is used for prophylaxis after hospital discharge (typically for orthopedic surgeries), it is necessary to do blood tests every 3-5 days to determine whether a therapeutic blood level has been achieved (or exceeded) and make adjustments in the dosage to achieve that level. Too low a level, and the drug is not effective in preventing clots, and too high a level can result in spontaneous bleeding or other complications.

## CASE ANALYSIS

The most common case we review involves a patient who underwent

surgery and then developed PE and died while in the hospital. In a few cases, the issue will be whether there were signs and symptoms of PE that were missed by the nurses or physicians. In most cases, however, the analysis will focus on whether appropriate prophylaxis was ordered and given.

The facts that must be analyzed are (1) nature of the surgery, (2) existence of other risk factors, and (3) type and timing of prophylaxis ordered. In effect, the attorney will be applying the risk stratification system outlined in the literature to determine, as an initial matter, whether it appears the care provided was below the standard. As noted above, a major surgery coupled with other risk factors will almost always trigger the need for prophylaxis, but even a minor surgery may do so if other risk factors are present.

As mentioned, a significant risk factor is whether the patient or an immediate family member has had clotting problems. If so, the likelihood of an inherited coagulopathy is great. In addition, if the patient has had a prior history of DVT, the likelihood of developing DVT is greater under conditions that might not pose a risk for a different patient. Thus, it is important that the health care provider take a good history. Failure to do so may be negligent. If your analysis shows a prior family history of coagulopathy or DVT, but this is not noted in the medical records, the failure to order prophylaxis after surgery may be a consequence of that lack of knowledge on the part of the physician.

Many cases will fall into the category of “under ideal standards in the literature, prophylaxis should have

been done, but it is not the accepted practice.” As noted earlier in this article, medical practice has not yet caught up with the standards established by the literature. It is possible you can prove your case under *Harris v. Groth*, 99 Wn.2d 438 (1983), a case that emphasized that the standard is that of a reasonable and prudent physician, not what other physicians actually do in practice (see, also, WPI 105.02), but that may be a difficult burden to meet.

Many other cases will be in the gray area of “in retrospect, prophylaxis would have been good, but it isn’t clear that it is required in that setting.” Many examples come to mind. One has to do with non-hospital settings: an individual suffers a foot fracture that does not require immediate hospitalization, and while he is at home a few days later dies from DVT/PE. If the patient had been in the hospital, it is possible that prophylaxis might have been given. After all, the patient suffered a trauma to a lower extremity (a risk factor) and he may be immobile for several days because of the need to not weight bear on the leg (another risk factor).

In the hospital setting, the physician should take a history that would reveal a family history of coagulopathy or other risk factors, but there is no literature that requires that kind of inquiry in an out-patient setting. There may also be a “falling between the cracks” problem. The ER physician who put the foot in a short cast and discharged the patient to wait for an appointment with a primary care physician or orthopedic surgeon may assume that the other physician will treat the patient once he/she is no longer in the ER, but the other physician may not be scheduled to see the patient until it is too late.



Another example is the provision of prophylaxis that falls short of preventing DVT/PE. For some surgeries, a physician may order sequential compression devices (SCDs) until the patient is ambulatory, assuming that commencing ambulation is sufficient itself to prevent DVT/PE. The nurse then walks the patient once to the bathroom, considers the patient to be ambulatory, and removes the stockings. However, the patient still experiences pain and is essentially immobile for the next 12-24 hours, and suffers a DVT/PE. The SCD stockings are often uncomfortable and patients decline to use them when offered by a nurse. Of course, an issue then is whether the patient fully understood the medical need for the stockings and made an informed consent to not wear them.

A more common problem is the patient who is discharged early from the hospital, a frequent scenario in today's world of HMOs and managed care. Depending on the severity of surgery and other risk factors, the risk of DVT/PE may continue for several days after the procedure (in the case of hip replacement surgery, as much as 714 days post-surgery). Many surgeons are not well-prepared to "manage" the patient's post-op care after the patient leaves the hospital, other than return office visits to check wound healing or remove sutures. There may be adequate prophylaxis while the patient is in the hospital, but the physician may assume that if the patient is somewhat ambulatory on discharge the need no longer continues. However, depending on pain tolerance and other factors, a patient may continue to be essentially immobile for several days after dis-

charge and the risk of DVT/PE may remain high.

This scenario is especially risky for same-day surgeries, such as those often performed by plastic surgeons in office operating suites. Some of those surgeries are lengthy and, because of the extent of surgery and use of general anesthesia, as well as pain leading to immobility, the risk for DVT/PE is significant. If the patient is discharged to a hotel room or his/her home from such a surgery, there may be no one trained to encourage and assist the patient to be ambulatory as soon as possible, or to realize that signs and symptoms of DVT/PE may be developing.

In one case, a plastic surgeon testified that she did not place a urinary catheter at discharge, and she felt this was sufficient "prophylaxis" for DVT because it would encourage the patient to walk to the bathroom. The patient died from massive PE the next morning in her hotel room. In Florida, there were enough DVT/PE deaths after in-office plastic surgeries, that legislation was proposed to ban lengthy or complex in-office procedures. Major national medical groups are also proposing standards to avoid the risks of DVT/PE from in-office surgeries.

## CONCLUSION

The number of deaths from DVT/PE each year exceeds the number of deaths from breast cancer. Deaths from "blood clots" are not a necessary risk of surgery or hospitalizations, and in many cases the deaths and injuries can be avoided through careful consideration of the patient's risk factors and the ordering of appropriate prophylaxis.

The fact that many providers remain unaware of this national health crisis, and fail to take reasonable steps to protect against it, means there are many cases where the plaintiffs' attorney can establish that care fell below the standards of a reasonable and prudent physician.

### Basic References:

- Geeris, et al., Prevention of Venous Thromboembolism, Chest, Vol. 119, No. 1, Jan., 2001.
- Hirsch, et al., Management of Deep Vein Thrombosis and Pulmonary Embolism, American Heart Association, 1996.
- Kaboli, et al., DVT Prophylaxis and Anticoagulation in the Surgical Patient, Medical Clinics of North America, Vol. 87, No. 1, Jan., 2003.
- Goldhaber, Medical Progress: Pulmonary Embolism, The New England Journal of Medicine, Vol. 339, No. 2, July, 1998.
- Anderson, et al., Best Practices: Preventing Deep Vein Thrombosis and Pulmonary Embolism, U.Mass. Medical School, 1998 [see [www.dvt.org](http://www.dvt.org)].
- Freedman, et al., A Meta-Analysis of Thromboembolic Prophylaxis Following Elective Total Hip Arthroplasty, Vol. 82, No. 7, July, 2000. o0o

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