CHAPTER 34

2007
Risk Management Lecture

Vascular Complications of the Lower Extremity

DISCLAIMER
The information presented in this lecture and contained in this document does not establish a standard of care. The information is for general informational purposes to aid in reducing professional liability exposure.

©2007 PICA Group®
PICA Vascular Complication Claims

- 1,974 PL claims closed 1/1/02 – 9/1/06
- Reviewed claims where vascular complications were likely at issue:
  - Alleged injury = prolonged tx, amputation, death, or pain & suffering
  - Risk Issue = failure to diagnose, diagnosis delay, failure to obtain approp. diagnostic testing, failure to obtain approp. pre-op work-up, complication/poor outcome, unclear/inadeq. pt. instruction, thermal injuries, failure to monitor, failure to treat
- Identified 96 vascular complication claims
Vascular Complication Claims: Alleged Injury

- Prolonged tx.: 10%
- Pain & suffering: 1%
- Death: 13%
- Amputation: 76%

Vascular Complication Claims: Complication Type

- Iatrogenic complications: 5%
- Other Vasc. Episodes: 13%
- DVT/PE: 17%
- PVD: 65%
Vascular Complication Claims: Statistics

- **Avg. Indemnity Payment** (all 96 vascular complication claims) – **$102,281**

- **Avg. Indemnity Payment** (vascular complication claims excluding claims with no indemnity payment) – **$251,022**

- **Avg. Total Claim Cost** (all 96 vascular complication claims, includes indemnity & expense cost) – **$156,812**
Vascular Complication Claims: Statistics

<table>
<thead>
<tr>
<th>Frequency of Indemnity Payments</th>
<th>Amount of Indemnity Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>48%</strong> of Vascular Complication Claims were closed with an indemnity payment</td>
<td>Avg. indemnity payment of Vascular Complication Claims closed with indemnity payment = $251,022</td>
</tr>
<tr>
<td>Vs.</td>
<td>Vs.</td>
</tr>
<tr>
<td><strong>37%</strong> of all 1,974 PL Claims were closed with an indemnity payment</td>
<td>Avg. indemnity payment for all PL claims that were closed with indemnity payment = $124,851</td>
</tr>
</tbody>
</table>
VASCULAR QUESTIONNAIRE

Patient Instructions: Please read the entire form and fill in the blank or circle the correct answer.

GENERAL
What is your Primary Care/Internal Medicine doctor’s name? ____________________________
What other doctors do you see?

Cardiologist? ____________________________
When was the last time you had a general physical examination? ____________________________
Do you think that you eat properly? Yes No
Do you get enough exercise? Yes No
How would you describe your general health? Excellent Good Fair Poor

ARTERIAL PROBLEMS
Certain “risk factors” put you at increased risk for developing arteriosclerosis (hardening of the arteries) which is the main cause of heart attacks, strokes and amputations. As a result you may not heal your foot surgery or you may develop complications from your present condition. That is why we ask the following questions.

Risk Factors:
➢ Do you now or have you ever smoked tobacco? Yes No
   At what age did you start? ____________________________
   At what age did you quit? ____________________________
   How much do you smoke now? ____________________________

➢ Do you have high blood pressure? Yes No
   How old were you when it was first diagnosed? ____________________________
   Have you ever had a major or minor stroke? Yes No
   If so, please comment ____________________________
   Please list your blood pressure medications, doses and frequency:

➢ Have you ever had heart trouble? Yes No
   Type of heart trouble? heart attack abnormal rhythm heart failure
   Date? ____________________________
   Do you have a pacemaker? Yes No
   Please list hospitalizations for the heart problems, including dates:

   Please list your heart medications, doses and frequency:

➢ Do you take medications to fight cholesterol? Yes No
   Please list your cholesterol medications, doses and frequency:

➢ Do you take blood thinners? Yes No What kind? Aspirin Plavix Coumadin Other:
   Why do you take blood thinners? ____________________________

➢ What is the most you have ever weighed? ____________________________ What do you weigh now? ____________________________
   What did you weigh when you were married? ____________________________
   Do you think of yourself as underweight, overweight, or about normal? ____________________________

➢ Have you ever been told that you have trouble with your circulation? Yes No
   Do you get cramps or fatigue in your legs when you walk? Yes No
   Right leg Left leg Both legs
   Do your feet hurt at night? Yes No
   Have you ever had any sores or ulcers on your feet, legs, or toes? Yes No
   Have you ever been treated or operated upon for circulation problems? Yes No

VENOUS PROBLEMS
Although varicose veins usually don’t interfere with foot problems, other diseases of the veins may put you at risk for developing ulcers or blood clots. The answers to these questions will help your doctor as he cares for your foot problems.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have varicose veins?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who in your family has varicose veins?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have swelling of your ankles?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the swelling go away at night or does it continue?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long have you had the swelling?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What do you do about it? Take diuretics (water pills) Use elastic compression stockings Other:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever had a “blood clot” in your leg(s)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If so, were you given blood thinners?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were you put in the hospital?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Did it happen after a pregnancy or operation?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever had an ulcer on your ankle?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever bled from a varicose vein?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If so, when did it begin?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever had a “blood clot” to the lung or heart?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How long were you treated for it?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have any “bleeding or clotting tendencies”?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**DIABETES**

Diabetes is a growing health care problem in America and poses special problems for Podiatry patients. By knowing more about your Diabetes your doctor can take better care of your feet and help you to take better care of yourself.

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have diabetes (“sugar”)?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How old were you when you were diagnosed with diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>How often do you (or someone) check your blood sugar?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Every day More than once a day Other:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>What do your morning blood sugars measure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you take pills to control your blood sugar?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you take insulin to control your blood sugar?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you know what an HGBA1c is?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you know what your HGBA1c is?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Who in your family has diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have they ever had a major health care problem because of their diabetes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If so, what kind of problem?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever had any trouble with your vision?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you ever had laser treatment for your eyes?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have any trouble with your kidneys?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you have any numbness, tingling, or burning of your feet?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**AND FINALLY...** Is there anything else you would like to tell me about your health?

<table>
<thead>
<tr>
<th>Patient Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Thank you for answering these questions. Working together, we can provide you with quality care.

This vascular questionnaire was developed by George Andros, MD for the 2007 PICA Risk Management Lecture.
Case # 1
Peripheral Artery Disease

Patient first presented to Podiatrist on 8/9/00. She came to see Podiatrist, because her daughter had previously been a patient of Podiatrist. At the time of the first visit, Patient was complaining of an ulcerated and abscessed corn on the right hallux. Her physical examination showed that she had an area on the right hallux that was abscessed. She had no pulses on the right and left posterior tibialis and no pulse on the dorsalis pedis on the right and 2+ on the left. A Doppler examination was performed at this time in the Podiatrist’s office. Podiatrist performed an incision and drainage of the abscess and prescribed Domeboro, Neosporin, Cephalexin and Vicodin.

By the time Patient returned on 8/16/00, the abscess had cleared showing at least some ability of the foot to heal. X-rays had been performed on the previous visit and an Austin Bunionectomy and lateral condelectomy of the right hallux was discussed and scheduled. Patient was consented for the surgery on this date even though it was not scheduled until 8/30/00.

On 8/30/00, Patient underwent an Austin bunionectomy with Orthosorb pin fixation on the right foot and a lateral condylectomy of the distal phalanx of the right hallux. An ankle tourniquet was used during the procedure. At the completion of the procedure, Patient was returned to recovery with no problems. It was noted in the operative report that following the release of the tourniquet that Patient had a return of her preoperative vascularity.

Patient presented for her first postoperative visit on 9/6/00. It was noted that Patient was having good progress and her right foot was redressed and an x-ray was performed. The next visit was on 9/11/00 when it was noted that Patient had mild central drainage from the bunion incision with dehiscence noted superficially. It was also noted that there was minimal cellulites. Patient’s sutures were removed and the foot was redressed with Neosporin ointment. A culture and sensitivity was taken. Patient was instructed on standard Betadine soaks, the use of Neosporin ointment was prescribed Mepergan fortis and Keflex.

Patient was scheduled to return for a follow up appointment on 9/13/00, but had to cancel due to the weather. Podiatrist made a house call on this date to see Patient and redressed her foot with Neosporin ointment. The note for this date indicates that home health is to continue with Betadine soaks, although the previous note does not mention that home health was ordered. Podiatrist also changes Patient’s oral antibiotic to Cipro.

On 9/15/00, Podiatrist received the results of the culture which showed a heavy growth of coagulase negative staph which was sensitive to the Cipro. It was also noted on this date that Patient was not improving. Podiatrist again visited Patient at her home after having received a phone call from the home health nurse who indicated that the foot was showing no improvement. On this date, Podiatrist sent Patient to Hospital for a wound care consultation. She was admitted on this date and Podiatrist performed a debridement
of the wound and engaged the services of a Vascular Surgeon who performed a right lumbar sympathectomy.

Patient underwent additional surgery on 9/19/00 which included a right superficial femoral and proximal popliteal balloon angioplasty and right femoral, popliteal and tibial thrombectomy. At the conclusion of the procedure it was noted that Patient's pulses were improved. However, on 9/25/00, Podiatrist performed a transmetatarsal amputation of the right foot due to the wound dehiscence with gangrene of the first, second and third toes of the right foot.

Patient was discharged home on 10/10/00 with home health. She was provided with a prescription for a wheelchair and a walker. Podiatrist visited Patient at her house on 10/11/00 and redressed the wound. It was noted that the suture line was dry and intact. Patient was instructed to only engage in light, limited and protected weight bearing.

Podiatrist returned to see Patient on 10/16/00. Her sutures were removed and this time and the wound was reinforced with steri-strips and redressed. It was noted that there was no drainage or cellulites. Patient was instructed to keep the foot dry and only engage in light weight bearing. A drop foot brace with shoe filler was prescribed.

Patient continued to improve and Podiatrist saw Patient on 10/30/00, 11/15/00 and 12/4/00. Patient was showing some hesitancy to bear weight and ultimately began wearing the shoe filler. Currently, Patient is not receiving any care related to her foot and has had no problems for which she has sought medical care relating to her foot in well over two years. She continues to ambulate well with the shoe filler.

Allegations:

- Failure to establish circulatory status prior to surgery
- Failure to perform Doppler study appropriately
- Failure to properly read Doppler study
- Performance of unnecessary surgery
- Failure to fully inform patient

Patient Age: 78
Sex: F
Disposition: Tried to Defense Verdict
Case # 2
Diabetic Patient with Vascular Compromise

The patient presented to insured with complaints of pain and numbness in her feet bilaterally. She was diabetic. She reported a history of hitting her left 5th toe on a chair one week prior to the visit. She stated she could not tolerate shoes. The insured diagnosed a fracture of the left 5th toe and treated her with rest, elevation, use of a wooden post-op shoe. The patient returned for follow-up in one week. At both visits, the insured documented non-palpable DP and PT pulses. The patient missed her next two appointments, then returned to the insured 28 days after her initial appt. The insured noted a healed fracture of the left 5 toe, but the toe was still swollen and painful. The insured prescribed Percocet and reappointed for one week. However, the patient did not return until 3 weeks later. She still complained of bilateral pain in her feet and pain in her right great toe from when she recently tried to trim her nail. The insured again noted non-palpable DP and PT pulses but noted that Doppler exam revealed pedal pulses bilaterally. The insured debrided the right great toenail and recommended an unna boot for the right foot. The patient was to return in one week, but did not show until one month later. At that visit, she had a puncture-type wound on the plantar aspect between the 2nd and 3rd toes of the left foot, but the patient could not recall stepping on anything. The insured diagnosed an abscess and cellulitis of the left foot, ankle and leg. He referred the patient to her family doctor. From the next three months, the insured treated the patient for the ulcer which apparently resolved. The insured was not able to palpate DP or PT pulses on any of these visits.

The patient returned to the insured five months later for treatment of an ulcer on the 2nd toe. He treated the ulcer with debridement and Keflex. A follow-up visit occurred three weeks later. The insured noted that the toe was swollen and dark in color. There were no DP or PT pulses and no Doppler exam was performed. The insured diagnosed dry gangrene of the left 2nd toe and PVD and reappointed the pt. for 3 weeks. When she returned, the insured noted that the toe was black in color and had an odor and was swollen. The insured referred the patient back to her family physician for hospitalization and amputation of the right 2nd toe.

Upon hospitalization, the patient was referred to a general surgeon who performed the amputation. The surgeon diagnosed the patient with femoral occlusive disease and small vessel occlusive disease. The patient was readmitted to the hospital a month later for chest pain, congestive heart failure, COPD exacerbation, anemia, PVD and status post second toe amputation. She was scheduled to undergo coronary bypass surgery, but the surgery was aborted due to possible residual infection at the amputation site. A below-the-knee amputation was performed a few days later. The pt. eventually had the coronary bypass surgery (6 bypasses).

Allegations:
♦ Failure to take an adequate history
♦ Failure to conduct an adequate physical examination
♦ Failure to perform appropriate diagnostic testing
♦ Failure to refer to appropriate specialists

Patient’s Age: 44
Sex: F
Disposition: Settled during mediation
Case #3
Deep Vein Thrombosis

The patient was seen by his primary care physician (PCP) for complaints of pain and swelling in his left lower extremity. The patient reported a history of leg and ankle edema and pain. The PCP diagnosed probable gout and referred the patient to the insured. At the first visit with the insured, the patient had been taking an anti-inflammatory medication prescribed by his PCP, but reported no relief. The patient's chief complaint was concerns over edema and swelling in his left lower extremity which seemed to get progressively worse. The patient also complained of ongoing pain in the left plantar fascia area of his foot. The patient had recently stopped smoking and had reportedly gained 40 pounds as a result. Based upon the symptoms as presented, the insured suspected that the patient suffered from plantar fascitis. He administered therapeutic injections for the purposes of pain management and to reduce swelling. Additionally, the insured prescribed a 3-week supply of Lasix hoping to aid in diurezing the fluid that gathered in the affected area. The insured saw the patient in follow up two weeks later. He noticed significantly reduced swelling in the patient's left leg and noted no complaints by the patient in the left plantar fascia of his foot as of that date. According to the patient during deposition, it was during his second visit with the insured in which he discussed the prospect of having developed a blood clot with insured. The patient claimed he discussed the possibility of DVT with insured and asked him for an ultrasound. He claims the insured told him an ultrasound was unnecessary and that he had “nicotine withdrawal syndrome.” The insured refilled the patient's prescription for Lasix, and suggested that he follow up with his primary care doctor if his condition worsened or failed to improve. A follow up appointment was also scheduled with the insured. However, the patient cancelled that appointment and was not seen by the insured again.

Two months later the patient presented to another doctor who noted swelling mostly around the patient's left leg between the knee and ankle, prompting him to order an ultrasound to rule out DVT. The ultrasound was performed the following day, revealing evidence of deep vein thrombosis involving the left popliteal vein. The patient was admitted to the hospital for treatment and a full work-up. A CT angiogram of the chest and lungs revealed pulmonary emboli involving both the right and left main pulmonary arteries. The patient subsequently received anticoagulation therapy.

The patient suffers from post-thrombotic and post-phlebitic syndrome, and has intermittent pain and swelling in his left leg. He is at risk for future development of DVT and pulmonary emboli.

Allegations:
- Negligence in failing to recognize the signs and symptoms of DVT
- Failure to diagnose DVT

Patient Age: 41
Sex: M
Disposition: Settled During Mediation
Case #4
Postoperative Pulmonary Embolism

The patient underwent a bunionectomy and saw the insured for routine post-op appointments for 6 weeks. At the last appointment, which was the patient's first day back at work, the patient reported feeling moderately anxious. The patient attributed her anxiousness to being back at work. She reported taking several breaks during the day due to discomfort. The insured advised the patient to continue monitoring her anxiety and to contact her primary care physician if her symptoms persisted.

The insured received a telephone call from the coroner the next day indicating the patient had died from a pulmonary embolism. The insured reported to the coroner that the patient had complained of “several anxiety attacks” described as shortness of breath and feeling anxious, but stated she would recover when she sat down. Insured also told the coroner the patient had “high” pulse and respirations, and that he asked the patient if she wanted to go to the ED, but the patient refused.

Although pulmonary emboli are extremely difficult to diagnose, there are certain warning signs including anxiety, difficulty breathing, and increased blood pressure and heart rate. The deceased presented to the insured with these symptoms mid-afternoon and died at home alone within a few hours of leaving his office. Although insured suggested during the visit that the deceased be evaluated at an emergency room, he did not insist or summon an ambulance.

Allegations:
- Failure to diagnose pulmonary embolism
- Failure to suspect pulmonary embolism and refer for emergency evaluation and treatment

Patient Age: 47
Sex: F
Disposition: Settled During Mediation
Case # 5
Iatrogenic Vascular Complications

The podiatrist performed a tailor's bunionectomy of the first and fifth rays of the right foot while using a local anesthetic comprised of lidocaine and epinephrine in a 1 to 1/200,000 ratio for a pre-surgery total of 35ccs of epinephrine. (The surgical records are not clear on how much epinephrine was administered.) A tourniquet was also used. Postoperatively, the patient received 3ccs of epinephrine (same dilution) with .05 percent marcaine and was prescribed a cold pack to be used one hour on and one hour off during waking hours. (The patient was on birth control pills.)

The patient was followed by telephone for two days after the surgery. The patient complained about foot numbness on both days. She was seen in the office on the 3rd postop day. Her toes were blue from the mid joint to the tip, but the top of the foot was not compromised. The podiatrist immediately recognized a vascular problem and consulted a vascular surgeon by telephone. The patient was placed on a vasodilator in order to relieve a suspected vasospasm. The patient was referred for an arterial Doppler. However the test could only measure the arterial blood flow down through the base of the ankle and not into the foot. The patient was instructed to return to the office the following day and to notify the ED and ask for the vascular surgeon if she had any problems in the meantime. The next day she presented to the ED where she was admitted and treated for vascular compromise of the plantar arch and metatarsal arch. She was placed on a course of streptokinase the next day. She eventually recovered, however, prior to her recovery, she was told by the vascular surgeon that there was a possibility she could loose her leg below the knee, then part of her foot, then her toes, then just a toe. She lived with the possibility of an amputation for several weeks.

The patient continues to have cold sensitivity, possibly related to Raynaud’s syndrome that manifested at the time of surgery. She claims she cannot walk for more than 20 minutes and cannot run. She also has to guard her foot against cold.

Allegations:
◇ Negligent use of epinephrine/lidocaine mixture and the epinephrine and marcaine for a local anesthetic. (The second round of injections with epinephrine and marcaine caused vasoconstriction of the vessels of the foot.)
◇ Failure to see the patient when she continued to complain of numbness 24 hours after surgery.
◇ The cold pack therapy contributed to the ischemic event.

Patient Age: 22
Sex: F
Disposition: Settled During Trial
CONSENT FOR TREATMENT

PERIPHERAL VASCULAR DISEASE/DIABETIC PATIENT

(Note: If surgery is to be performed, this form is to be used in conjunction with a surgery consent form.)

I understand that I have poor circulation and this is a condition that may/will get worse. I know that I have a risk of disease or complications because I have poor circulation, even with professional care and treatment.

I understand that I have the following treatment options:

1. No treatment
2. Special/wider shoes
3. Padding
4. Soaks
5. Periodic treatment to make me more comfortable
6. Antibiotics and/or other medications
7. Limit my walking/weight-bearing time
8. Change in occupation
9. Surgery
10. ___________

I understand that with any treatment of my condition, including surgery, the following risks are present:

1. Infection
2. Delayed healing
3. Wound deterioration or breakdown
4. Additional danger of artery/vein clotting (blood clot)
5. Skin tissue death/skin ulcer
6. Loss of toe, foot, limb, or life
7. Drug reaction
8. ___________

These risks are present in all operations/treatment. However, I understand that my poor circulation increases my risk for complications. If I have one or more of these complications, I UNDERSTAND THAT MY FUTURE CARE AND TREATMENT MAY BE MORE DIFFICULT AND THE OUTCOME MORE UNCERTAIN.

NON-TREATMENT OF MY FOOT PROBLEMS also presents serious risks to me. My foot problems could get worse, and I might have new complications such as infection, skin ulcer/breakdown and loss of toe, foot, limb, or life.

I certify that I know or have been informed that I have a systemic condition (peripheral vascular disease/diabetes). My podiatrist has advised me to see a vascular surgeon or other medical specialist. I UNDERSTAND AND ACKNOWLEDGE MY PODIATRIST WILL TREAT ONLY MY FOOT (and ankle) CONDITIONS AND WILL NOT TREAT DIRECTLY MY SYSTEMIC CONDITIONS (peripheral vascular disease/diabetes).

My podiatrist has explained the above information and the alternatives/material risks to me, I understand this explanation, and I authorize my podiatrist to treat my foot condition(s).

Patient Signature ___________________________ Date ________
Witness ______________________________________ Date ________
Physician Signature __________________________ Date ________

Revised May 2006