



120 Beulah Road, NE, Suite 200
Vienna, Virginia 22180
Toll Free: 800-336-0332
Fax: 703-255-6134
www.malpracticeexperts.com

Vascular Surgery Sample Case

Carotid artery endarterectomy with bovine pericardium patch graft, infection, hemorrhage and death.

The carotid arteries, one on each side of the neck, supply 80 percent of the arterial oxygenated blood to the brain. There is normally a cross connection between these two arteries at the base of the brain, called the Circle of Willis. If one carotid artery is blocked by a build up of cholesterol, called an atherosclerotic plaque and the other one is open by 30 percent or more, usually the blood flow is adequate. But if both only have a small opening, then even in the absence of symptoms, surgery is justified to prevent a potential stroke.

This patient was advised of the 3 percent risk of stroke with surgery, and 10 percent risk over time with conservative care. He was taking the anticoagulant (blood thinner) Coumadin which is the standard of care, particularly because of the severe atherosclerosis involving his legs and the artery bypass grafts to his right leg nine years before. He was also taking a cholesterol-lowering drug, for an unknown amount of time, with an unknown effect on his blood cholesterol. I have not seen those records.

Dr. #1, his Surgeon was performing ultrasound (doppler blood flow studies using sound waves) to monitor his diseased carotid arteries blood flow. The carotid arteries had "bruits" when listened to using a stethoscope because the stenosis (hourglass deformity) causes a whistling sound, which was noted in the surgeon's office records. The blood flow is altered and that is the basis for the ultrasound study.

The ultrasound study showed 15-20% stenosis on the right and 40-50% on the left.

The next year it increased to 25-30% on the right and 45-55% on the left.

The next year it was 25-30% on the right and was 30-35% on the left. The study is a rough guide, and if indicated, the arteriogram (artery x-ray dye study to evaluate the inside of the artery, the "gold standard") can be done as it was subsequently performed three years later.

The next year the right side stenosis increased to 30-35% and the left was 35-40% by ultrasound.

Another way of determining the degree of blood flow impairment is to calculate the ratio of blood flow in the internal carotid artery (going to the brain) divided by the common carotid artery blood flow (going to the face through the external carotid artery branch plus the internal carotid artery). This is the ICA/CCA ratio. On the right side which was finally operated on, the ratio was first documented to be 1.53 (minimal impairment of flow), in the next year it was 1.26, in the next year it was 1.27, in the next year it was 1.29, but two years later it was very high at 7.17. This was a critical stenosis which markedly impaired blood flow and could suddenly block off. The left side had a value of 2.15 which is a moderate to severe stenosis.

To further evaluate this stenosis he had the arteriogram study on March 23. Dr. #1 performed the study and confirmed the critical stenosis on the right and a severe stenosis on the left. His drawings show what he found. The Radiologist also evaluated these x-rays and found that the stenosis on the right was greater than 95% and had plaque formation (irregular interior from atherosclerosis, increasing the risk of blood clot formation), and at least 90% narrowing on the left. This confirmed the previous evaluation.

The patient was informed of the 3% risk of stroke with surgery and 10% risk without the operation to clean out the blockage (carotid endarterectomy). I do not know if he was informed of other risks such as infection, bleeding and death. If he was not, that would be lack of informed consent. But the overall risk was greater without surgery, and the operation was indicated.

The plan was to operate on the right side and then the left side a few months later. That was reasonable.

A Cardiologist evaluated this patient as a surgery candidate on April 28, modified his blood pressure medication and felt that his coronary (heart) artery disease was "stable". He was also taking the anticoagulant Coumadin as 10 milligrams daily and 15 mg. on the weekends. This was discontinued a few days before surgery as was proper, but the note by the surgeon said he had been taking 5 mg. per day, which is in error.

The operation took place on May 8, and after using the iodine skin preparation to try to sterilize the skin, the surgery was done in the standard manner with the use of a temporary shunt (blood tube conduct inside the artery to maintain blood flow to the brain during most of this operation). The surgeon said: "...because of the size of the artery we elected to use an oval piece of Bovine (cow) pericardium (heart sac) which was then sutured to the artery...". This allows the artery to be sutured closed without narrowing its hollow passageway (lumen). It should have been obtained by the supplier ("manufacturer") sterile and its sterility tested and maintained.

The Pathologist confirmed that "the vessel wall shows heavy atherosclerotic changes including calcifications (bone like changes)".

The patient awoke after surgery and had no neurological damage (stroke). He was discharged home on May 10 "on Coumadin", but I do not know what dose. He "left for home with scripts (prescriptions) and instructions which he understands".

I have not seen any further office or hospital records except for a few laboratory reports. They show that there was not any overdose effect from the Coumadin (The INR was 1.07 on May 17, which shows very little Coumidan anticoagulation effect). He came in anemic from blood loss (HCT of 31) that became dangerously low (25) by 1:30 pm on May 17. It increased to 27 on May 18 and to 28.8 on May 19. I do not know how much blood he received, but this amount of anemia is dangerous for a cardiac patient.

The blood clot (hematoma) and carotid graft site had tests for germs (culture and sensitivity studies) and both showed the presence of the germ "coagulase negative staph". This is a common skin germ but can be pathologic (cause infections) in the body, as it appears to have done here.

Without seeing the in hospital records from May 17 through his death on May 22, I will give you some opinions that may change when all of those records are supplied.

When a graft site becomes infected, there is a risk of rupture of the suture line, which results in massive bleeding into the neck. Sometimes there is leakage with local pain and swelling increasing over time, and that requires urgent hospitalizations and tests such as a CT Scan, MRI and/or arteriogram to confirm the diagnosis, and emergency surgery to control the bleeding, to prevent death.

It is possible that the Bovine pericardium patch graft was not obtained under sterile conditions or not properly handled and sterilized. This would be a manufacturer product liability problem. Possibly the hospital violated sterile precautions and technique in opening the package.

There is always the possibility that the surgeon's or assistant's glove tore from a needle stick and contaminated the operative site. That can happen in the absence of negligence.

I do not know if prophylactic (preventive) antibiotics were used. If this was surgery to put in a synthetic graft, or artificial hip, for example, then antibiotics are given immediately prior to surgery, and for one or two days thereafter. With a small piece of Bovine pericardium, which is natural flesh, in my opinion, antibiotic use would normally be optional. However, he was a diabetic on insulin, which means that he was much more susceptible to infection, and there would be more reason to use prophylactic antibiotics. Others would say that this was a "judgement call".

In addition, to the question of product liability, I do not know how long he was on cholesterol lowering medication. This would be especially important in his case, since he had severe known vascular disease with arterial grafts inserted ten years earlier, and because of his diabetes which causes atherosclerosis (cholesterol deposition in the walls of all arteries including his heart and carotid arteries) whose disease was known for some years. The failure to try to control his blood cholesterol level would be negligent.

It may be worthwhile to review the May 17-22 hospital records to determine if there were any departures from the standards of care, including failure of timely transfusions that may have caused or increased his risks of dying.

The office records of his medical doctors, including #2 and the Cardiologist Dr. #3, both Osteopathic Physicians, should be obtained to determine how they treated his elevated cholesterol. Without progression of his carotid artery disease, he would not have had that operation, whose delayed complication resulted in his premature death.

Was an autopsy performed? If it was obtain a complete copy of that report.

After review of those missing records, it may be reasonable for us to obtain opinions by Experts in Infectious Disease, Cardiology and Vascular Surgery, pursuant to our current Fee Schedule.