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Medicolegal Aspects of Headache Medicine

Case Studies

CASE 1
The Well-Intentioned Triptan Prescriber

A 54-year-old man with an active 1 pack per day smoking history, a history of coronary artery disease (status-post stenting), and chronic cluster previously refractory to a wide variety of therapeutic interventions (including gamma knife radiosurgery) presents complaining of cluster attacks that recently had worsened in their frequency and pain intensity. His prophylactic regimen included verapamil, lithium, topiramate, and methylergonovine. Each day over the previous 6 weeks, he had taken 1-3 tablets of sumatriptan 100 mg for incipient cluster attacks, and every night he had administered sumatriptan 6 mg subcutaneously for attacks that awakened him from sleep.

Advised by his treating physician that he was overusing sumatriptan and that he must cut back on his use/frequency of the drug, he replied, "Doc, I'd rather die." His wife confirmed that he had threatened suicide consequent to the recent exacerbation of cluster, and she had felt compelled to hide the key to his gun cabinet.

The patient was instructed to increase his dose of verapamil, begin taking melatonin 12 mg qhs and to start a 2-week tapering course of prednisone. A serum testosterone level was low, and he was treated in clinic with intramuscular injections of testosterone gel. His prescriptions for sumatriptan 100 mg tablets no. 27 and injectable sumatriptan 6 mg no. 27 were refilled; at the patient's request, the treating physician previously had obtained from the insurance carrier involved authorization for monthly quantities of sumatriptan higher than those typically allotted.

During the next 48 hours, the patient took 2 doses of sumatriptan 100 mg po and administered sumatriptan 6 mg subcutaneously on 3 occasions, the last 2 for a nocturnal cluster attack that atypically persisted following the initial injection. That attack was complicated by acute chest pain, and he was transported to the emergency department (ED) via EMT. At the ED, his blood pressure was 180/116, and electrocardiogram findings were consistent with acute anterior and inferior myocardial infarction. The patient survived and subsequently underwent coronary angiography and coronary artery bypass and grafting.

The neurologist treating his cluster was sued for simultaneously prescribing methylergonovine and sumatriptan and for willfully prescribing excessive amounts of the latter; both drugs were purported to have precipitated the patient's acute myocardial infarction.

QUESTIONS

1. *Does the plaintiff's assertion that his myocardial infarction resulted from triptan therapy meet the rule for medicolegal causation?*
2. *Do any of the specifics of this situation (the severity of the patient's headache disorder and its lack of response to prophylactic therapy; the threat of suicide; the patient's decision to administer triptans as he wished, regardless of his physician's advice and recommendations) serve to reduce or eliminate the treating physician's liability?*
3. *What, if anything, could the treating physician have done to manage this patient in a manner that would have met the patient's needs without exposing himself to the allegation of malpractice?*

MEDICAL COMMENTARY

Question.—*Does the plaintiff's assertion that his myocardial infarction resulted from triptan therapy meet the rule for medicolegal causation?*

Answer.—It is quite likely that the triptan contributed to this patient's myocardial infarction, especially given the coadministration of sumatriptan and methylergonovine, and the timing of the acute myocardial infarction—occurring almost immediately after the administration of 3

successive doses of subcutaneous sumatriptan. The fundamental guiding principle here is *Primum non-nocere*—first do no harm. The physician knew that the patient was using excessive amounts of sumatriptan (1-3 100-mg tablets plus a 6-mg subcutaneous injection in each 24-hour period), discussed this with him, and yet continued to prescribe excessive amounts against his better judgment. What he failed to disclose to the patient is that there is an absolute contraindication to the use of any triptan in patients with ischemic heart disease, and moreover, an absolute contraindication to the use of any triptan within 24 hours of ergots. It is not even clear that he disclosed to the patient why he was concerned about his excessive use of sumatriptan.

Question.—*Do any of the specifics of this situation (the severity of the patient's headache disorder and its lack of response to prophylactic therapy; the threat of suicide; the patient's decision to administer triptans as he wished, regardless of his physician's advice and recommendations) serve to reduce or eliminate the treating physician's liability?*

Answer.—Not in my opinion. While the patient may wish to continue to administer triptans against the advice of his physician, this physician has a responsibility to ensure the safety of his patient and should not have provided him with a triptan, supported the excessive use of sumatriptan by appealing to his insurance company for authorization to increase his supply of sumatriptan beyond the conventional allowable amount, and allow him to continue to use an ergot on a daily basis.

Question.—*What, if anything, could the treating physician have done to manage this patient in a manner that would have met the patient's needs without exposing himself to the allegation of malpractice?*

Answer.—First, the physician should explain the reasons why he can no longer prescribe sumatriptan for this patient. Specifically, a discussion regarding the absolute contraindications involved with the use of sumatriptan in his particular case and the risk of serious cardiovascular outcomes, including death.

Second, methylergonovine should have been discontinued immediately.

Third, he should have considered whether any other exacerbating condition was present. Specifically, the possibility of obstructive sleep apnea, which may occur in up to 50% of cluster headache patients, should have been assessed. This is a treatable condition and nasal continuous positive airway pressure may be effective for cluster patients with nocturnal attacks.

Fourth, he should review the medical and surgical options still available to the patient, beyond the use of sumatriptan.

- For acute treatment, safe and potentially effective alternatives include 100% oxygen at a flow rate of 8-15 liters per minute for 15 minutes and/or intranasal lidocaine.
- As a transitional measure, providing the patient with an occipital nerve block (2-3-cc 0.5% bupivicaine with or without 10-20-mg methylprednisolone) may have provided a reduction in the frequency of attacks until the effect of altering his preventive regimen became evident.
- Adding melatonin, prednisone, and increasing his dose of verapamil were reasonable in this patient. There is little evidence to support the use of testosterone in this patient and rather than this, either his dose of topiramate could have been increased or an alternative anticonvulsant added such as gabapentin or divalproex sodium.

Finally, in a patient who has threatened suicide, psychiatric consultation should be considered. The patient should also be reassured that other medical therapies exist, and surgical options are available should he prove to be medically recalcitrant.

There is a paucity of evidence concerning the safety of triptans or lack thereof in patients with established cardiovascular disease, specifically coronary artery disease. In fact, in a recent consensus statement on the cardiovascular safety of triptans, a heightened risk of serious cardiovascular adverse events in patients with coronary artery disease *did not* constitute the reason that the panel confined their conclusions to those without known coronary artery disease.[1] Rather, the panel cited a lack of compelling evidence that serious cardiovascular adverse events with triptans are more likely to occur in patients with coronary artery disease than in those without known coronary artery disease. Isolated, serious, cardiovascular adverse events have occurred in both groups of patients. The panel restricted their conclusions about the cardiovascular safety of triptans to those without coronary artery disease because the vast majority of data reviewed by the panel applied to this patient population. Those data show that, *among patients without known or suspected coronary artery disease, the safety profile of triptans is well defined and appears to reflect a very low risk of serious cardiovascular adverse events.*

The problem of course is that proving a negative is almost impossible when adverse events occur so rarely

because the sample size required to show a significant risk would be prohibitive. Although small numbers of patients with stable cardiovascular disease have been safely challenged with triptans, these data do not establish their safety in this population.

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CASE 2
The Broken Contract

A 42-year-old man presented to a physician for chronic migraine that had proven refractory to all conventional oral prophylactic agents (including various beta blockers, amitriptyline, divalproex sodium, topiramate, and verapamil), suboccipital blocks, and Botox injection therapy. He reported that he was functionally disabled by headache intensifications on an average of 15 days per month and that he consequently had been fired from his job as foreman at a local chemical plant.

After having the patient sign a "controlled substances agreement" that clearly stipulated the patient was not to receive analgesic medication, sedative/hypnotics or any schedule III medications from another source, was not to abuse alcohol, and was not to drive or operate heavy machinery after imbibing any amount of alcohol, the physician then prescribed methadone 5 mg tid for headache suppression. She also prescribed an oral triptan, naproxen sodium, and injectable sumatriptan for acute headache treatment.

At his return visit one month later, the patient reported that he was tolerating methadone well and had experienced a significant reduction in the frequency and severity of his headaches. At his 3-month follow-up visit, he reported that he was essentially headache-free and had returned to work on a full-time basis.

Unbeknownst to the treating neurologist, the patient was abusing alcohol and receiving prescriptions for hydrocodone, oxycodone, diazepam, and alprazolam from other physicians.

On a Saturday evening 5 months after he had begun taking methadone, the patient lost control of his vehicle while driving at high speed on an interstate highway, crossed the median strip, and struck another vehicle head-on. The patient sustained only minor injuries, but the front seat passenger in the other vehicle died consequent to cerebral contusions and transtentorial herniation, and the driver suffered a spinal cord injury from thoracic spine fracture/dislocation that resulted in permanent paraplegia.

At the time of his evaluation in the ED, the patient was found to have an elevated blood alcohol and a toxicology screen positive for benzodiazepines and opioids.

The paraplegic driver and the family of the deceased passenger sued the treating neurologist for her failure to adequately monitor her patient after prescribing methadone and, specifically, for failing to obtain toxicology screens on a regular basis to exclude the patient's use of other medications and substances that might impair his ability to drive.

QUESTIONS

1. *Did the treating physician have a medical (and medicolegal) responsibility to regularly perform screening tests intended to detect whether the patient concomitantly was taking medications that might exacerbate any side effects associated with chronic methadone therapy and, specifically, impair the patient's ability to drive?*
2. *Does the existence of a written contract which stipulated the patient was not to obtain analgesic drugs or other medications with the potential for abuse from another source, not to abuse alcohol, and not to drive after imbibing any amount of alcohol serve to relieve the treating physician of any potential liability in this case?*
3. *How can physicians who prescribe opioids for acute headache treatment, chronic headache suppression, or both do so safely (from both the medical and medicolegal standpoints)?*

LEGAL COMMENTARY

Question.—*Did the treating physician have a medical (and medicolegal) responsibility to regularly perform screening tests intended to detect whether the patient concomitantly was taking medications that might exacerbate any*

side effects associated with chronic methadone therapy and, specifically, impair the patient's ability to drive?

Answer.—The treating physician is most likely not liable unless he administered methadone to the patient in an impaired condition, or if he knew or should have known that the patient was using methadone to become intoxicated. There is no Alabama law directly on point to answer this question; however, there is a case holding that a physician could be liable for dispensing methadone to a known opiate abuser who was clearly mixing methadone with other narcotics in direct violation of the methadone clinic's established procedures.

LEGAL ANALYSIS

On March 12, 2004, in the case Lola Ann Taylor and Billy J. Taylor vs Dr. Kenney Smith, the Alabama Supreme Court ruled that a physician dispensing methadone in order to treat a patient's addiction to marijuana and benzodiazepines could be liable for injuries that the patient inflicted upon nonpatient third parties. The Alabama Supreme Court determined that Dr. Smith had a legal duty to dispense methadone in a reasonably prudent manner, or become liable for all damages proximately caused by his breach of this duty. Dr. Smith was the Medical Director of the Gadsden Treatment Center.

Under Alabama law, the existence of a duty is strictly a legal question to be determined by the court, as opposed to a factual question to be determined by the trier of fact (ie, jury or judge in a bench trial). In order to determine the existence of a duty, the court analyzed a number of factors including:

1. the nature of the defendant's activities;
2. the relationship between the parties; and
3. the type of injury or harm threatened. The court reiterated the key factor is whether the injury was foreseeable by the defendant.

The Court noted during Dr. Smith's 6-month treatment of Glenda Ennis, that 13 of the 14 urinalyses revealed the presence of marijuana, benzodiazepines, or both in addition to methadone. It should have been clear to Dr. Smith that Ennis was using methadone concomitant with other opiates; however, instead of dropping Ennis from the program, Dr. Smith continued to provide her with methadone. The Court also relied on an affidavit from Dr. Nathan R. Strahl, medical director at Raleigh Methadone Clinic, in which Dr. Strahl stated "combining methadone with benzodiazepines and marijuana can cause serious and potentially dangerous side effects. These side effects include, but are not limited to, poor concentration, drowsiness and sedation. A reasonably foreseeable consequence of an individual operating a motor vehicle while combining methadone and benzodiazepines and marijuana is that a vehicle accident may occur and other persons may be injured. A medical director of a methadone clinic should have knowledge of this."

In Florida law, this area is no different. In 2003, the Florida District Court of Appeals held that Dr. Joseph E. Dorsey and the Pompano Treatment Center could be held liable for administering methadone to their patient, Richard Reutlinger, when Reutlinger was under the influence of prescription and nonprescription drugs. On March 11, 1994, after Dr. Pompano administered Reutlinger's usual dose of methadone, Reutlinger was involved in a car accident that resulted in the deaths of Jeffrey Williams and Trevonda Williams. It was determined that Reutlinger was too impaired to operate a motor vehicle and that the methadone-induced impairment was the proximate cause of the ensuing accident. The Florida Court of Appeals found that there was substantial evidence that Dr. Dorsey and the clinic breached their duties of care by: (1) failing to properly conduct a drug screen urinalysis on Reutlinger; (2) failing to institute and follow policy and procedure for patient management while providing methadone treatment to Reutlinger; and (3) failing to provide proper screening of Reutlinger on March 11, 1994, which would have alerted the staff to Reutlinger's impaired condition and led the staff not to have administered methadone.

Importantly, the Florida District Court of Appeals found that Dr. Dorsey's administration of methadone was different from a situation where a patient obtains medication and then fails to follow warnings that the prescribed medication can affect the patient's motor skills and can become especially dangerous if mixed with other drugs or alcohol. The Florida Court of Appeals specifically noted that while administering methadone, the patient is within the treating physician's control and the patient's condition is readily available to the treating physician. The Court specifically stated that when one administers a drug that, when combined with other drugs or alcohol, may severely impair the patient, the doctor's failure to take the proper precautions (ie, verify whether the patient is already under the influence of another drug) is an "affirmative act which creates the risk that unidentifiable third parties might be injured. Under these circumstances, there is most certainly, a duty to unidentifiable third parties who may be injured as a result." Here, the physician's liability is not as clear-cut as the physicians' liability in the Alabama and Florida methadone clinic cases. Here, the treating physician is not using methadone to

treat opiate addiction; instead, methadone is being used to treat migraine headaches. There appears to be no evidence that the treating physician in this case study knew that the patient was abusing alcohol, opiates, or other narcotics that, when combined with methadone, could significantly impair the patient's ability to operate a vehicle. Here, unlike the Alabama and Florida cases, the methadone treatment was significantly improving the patient's condition. The patient had become "essentially headache-free and returned to work on a full time basis." Accordingly, the patient was not taking methadone simply for the purpose of drug abuse.

Ultimately, this case would hinge upon whether the treating physician had a duty to implement drug testing during his administration of methadone to the patient. The presiding judge would make this determination and would base his decision on the 3 factors listed supra. In my opinion, it is more likely than not that the judge would find that the treating physician was under no duty to implement drug testing procedures. A finding to the contrary could have devastating consequences to the medical profession. The prescribed methadone treatment was not for drug addiction or alcohol abuse, there is no evidence the patient was under the influence of drugs or alcohol at the time methadone was administered, and the methadone treatment was working well. Holding the treating physician liable for the patient's alcohol and drug abuse, outside of the treating physician's care, could result in every treating physician becoming liable for any injuries their patients cause while under the influence of prescription and other drugs anywhere in the world. Such an unrestricted holding would skyrocket medical costs and insurance rates and create a duty for treating physicians to police their patients 24 hours a day and all over the world. Clearly, such a duty is not practicable, reasonable, or attainable.

Question.—*Does the existence of a written contract which stipulated the patient was not to obtain analgesic drugs or other medications with the potential for abuse from another source, not to abuse alcohol and not to drive after imbibing any amount of alcohol serve to relieve the treating physician of any potential liability in this case?*

Answer.—Most likely yes, assuming that there is no evidence of drug or alcohol abuse combined with methadone. The treating physician's duty is simply to adequately warn the patient of the inherent dangers of methadone when mixed with alcohol or other drugs. The warning should be clear and communicated in a manner in which the patient can understand the inherent dangers of combining methadone with other drugs or alcohol.

Question.—*How can physicians who prescribe opioids for acute headache treatment, chronic headache suppression, or both do so safely (from both the medical and medicolegal standpoints)?*

Answer.—From a legal standpoint, physicians can limit their exposure to liability by taking precautionary steps to determine whether their patients are obtaining methadone for the purposes of mixing it with other drugs or alcohol. Physicians should ask detailed questions about the patient's drug and alcohol history and look for objective signs that may contradict the patient's responses (eg, symptoms of alcoholism, needle marks, unstable employment, emotional problems, etc). Obviously, if the patient exhibits signs that he is under the influence of drugs or alcohol, then the physician should refuse to treat him with methadone and the physician should warn the patient, in writing, that no further methadone will be administered if the patient again seeks methadone treatment in an impaired state. For these patients, the physician should consider requiring the patient to submit to urinalysis before administering methadone treatment. However, the danger in implementing a urinalysis program is that the physician may be undertaking a duty of care that he did not earlier have. Once the physician implements a drug screening program, then he must use reasonable measures to ensure program compliance, or else he may be liable for his failure to do so. As shown in the Alabama and Florida cases, failure to follow established precautionary procedures can lead to tremendous legal exposure.

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CASE 3
The Steroid Complication

A 60-year-old woman presented with a long-standing history of chronic migraine with an associated cervicogenic component. On initial examination, the physician found marked tenderness to palpation at the skull base in the

region of the occipital nerves bilaterally. He performed bilateral suboccipital nerve blocks, injecting triamcinolone 20 mg and bupivacaine 5 cc into each side.

The patient reported dramatic and sustained relief from her headache following the procedure, and this improvement persisted for 6 weeks. At that time, the physician again administered the nerve blocks, and the patient again enjoyed a period of headache relief that extended for almost 2 months.

Over the ensuing year, the treating physician continued to perform bilateral suboccipital nerve blocks at irregular intervals that varied from 4 weeks up to 3 months. Prior to her initial blocks and at intervals thereafter, the physician informed the patient that even short-term use of steroids has been associated with various complications, specifically including "avascular necrosis."

Shortly following her last blocks, the patient called to report that she was experiencing acute, severe hip pain that extended down the anterior aspect of the thigh. A hip X-ray performed later that day demonstrated a trochanteric fracture, and at the time of the patient's subsequent open reduction/internal fixation surgery, there was pathologic evidence of aseptic necrosis.

The patient sued the treating physician for having administered steroid therapy without advising her of the attendant risks and, more specifically, for having precipitated the patient's fracture.

QUESTIONS

1. *How great is the risk of aseptic necrosis to patients when steroids are administered infrequently and for restricted periods of time?*
2. *Should patients be apprised of this risk each time steroids are prescribed? If so, how detailed and well-documented should the process of such advisement be?*
3. *Does such verbal "informed consent" as was provided in this case relieve the treating physician of liability if the complication does occur?*

MEDICAL COMMENTARY

Question.—*How great is the risk of aseptic necrosis to patients when steroids are administered infrequently and for restricted periods of time?*

Answer.—Unfortunately, there is no answer to this question. Aseptic necrosis (osteonecrosis) of joints has many causes and many factors may interact to increase or decrease the risk.[1] This condition may also occur spontaneously on an idiopathic basis in patients who have never received corticosteroid treatment. It also may occur in association with many other conditions including trauma, alcoholism, infections (including HIV and possibly in association with the HAART), storage diseases, hyperbaric exposures, gout, hyperlipidemia, coagulopathies, renal failure, and autoimmune diseases.[1,2] Insufficient arterial blood supply leads to death of osteocytes and marrow cells, which eventually leads to a progressive collapse of bone.[1]

Aseptic necrosis may affect numerous joint, particularly the hips, knees, and shoulders. It is felt that some underlying conditions such as systemic lupus erythematosus may make the patient prone to have an increased risk when exposed to steroids, and the aseptic necrosis may occur with a lower cumulative dose and in a shorter time.[1,3] Steroids in part may trigger this process by inducing hyperlipidemia; there is even some evidence that "statins" may lower the risk.[4] There are many cases where long-term exposure to corticosteroids has not caused aseptic necrosis and some case reports of it occurring after just a single exposure.[1,5] Clearly in a given individual, a threshold dose and duration of exposure cannot be unequivocally stated.

In the absence of underlying conditions which might in and of themselves be associated with an increased likelihood of aseptic necrosis, it seems quite unusual to occur with less than 18 days of exposure and with a cumulative dose less than the equivalent of 2000-mg methylprednisolone.[6,7] When osteonecrosis occurs, it is important to search for all possible contributing causes.

Question.—*Should patients be apprised of this risk each time steroids are prescribed? If so, how detailed and well-documented should the process of such advisement be?*

Answer.—It is my practice to discuss any new/first-time procedure with the patient and then have them also sign an informed consent document. I discuss the nature of the procedure, why we are doing it, what we hope to accomplish (our therapeutic "target") by doing it, and common adverse events. I also discuss serious potential side effects even if they are uncommon and aseptic necrosis would qualify as that sort of adverse outcome. I both use the medical terms and explain the potential problems in "layman's terms." In this case, I also tell them that if osteonecrosis occurs, they might require joint replacement surgery which is an expensive and major undertaking. The patient is given as much time as they require to ask questions and decide if they wish to proceed with the procedure. Once they are satisfied with the process, they then sign an informed consent document which also includes both the medical terms as well as "lay-

man's terms" and the same information we discussed. For subsequent performances of the procedure, I record any benefits and adverse events reported by the patient and whether they gave verbal consent to repeat the procedure. Patients are instructed to report any good or bad outcomes as soon as they are aware of them. I periodically remind patients of potential adverse events that might occur with repeated performance of the procedure and document the discussion.

Question.—*Does such verbal "informed consent" as was provided in this case relieve the treating physician of liability if the complication does occur?*

Answer.—I believe that written documentation of the consent, signed by the patient and a witness, remains important. It provides clear evidence of what information was made available to the patient before a decision to proceed with treatment was made. Simply recording a verbal conversation in the chart opens up the possibility of differing interpretations and recollections of what was discussed. Therefore, written documentation is preferable but alone is not sufficient. The procedure still must be performed competently, with a reasonable indication, and appropriate follow-up care and monitoring is necessary. Increased vigilance would be particularly appropriate for patients with additional medical conditions known to increase the risk of developing aseptic necrosis of joints.

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LEGAL COMMENTARY

Though avascular necrosis, or osteonecrosis, is well recognized as a complication of prolonged steroid therapy, it has only more recently been recognized as a complication of short-term steroid treatment.[1-5] And, though it may be perceived to be a "rare" complication, whose precise risk may never truly be known nor predictable, the mere presence of such a risk is potentially problematic for a physician.

Regardless of which side of the "fence" the lawyer is on, his first job is to educate himself as completely as possible in reference to the involved medicine. Such an analysis requires a surgical dissection of every aspect of this potential "medicolegal" issue so as to properly represent the interests of those involved.

The first question to ask is whether the identified treatment works. Is the risk to the patient justified by "proven" scientifically reliable medical research? If not, what is the prevailing community standard of care?

There is certainly literature available supporting the efficacy of triamcinolone injection, for example, to treat adhesive capsulitis in the shoulder. There is similarly some literature supporting the proposition occipital nerve blocks can be helpful in treating headaches related to, for example, traumatic brain injuries. But, there is little available to "prove" bilateral suboccipital nerve blocks, injecting triamcinolone, actually work to alleviate migraine. While patients and physicians alike report benefits achieved, the lack of randomized scientific study creates a definite "obstacle" in reference to proving the efficacy of the treatment provided.

Whether defending or prosecuting a prospective claim, an understanding of aseptic necrosis is critical. The information the lawyer is able to glean from the research as a layman is the same information that should be provided to the patient in some form to avoid prospective exposure. Aseptic necrosis involves impaired blood supply to the bone, but, of course, it is not always clear what causes this impairment of blood supply. There is a plethora of literature describing the relationship between long-term systemic steroid use and aseptic necrosis or osteonecrosis. Excessive alcohol intake is another known risk factor for aseptic necrosis. The research seems to indicate steroids may interfere with the body's ability to break down lipids, ie, fatty substances. These fatty substances then build up in and clog the blood vessels,

causing them to narrow and to reduce the amount of blood that gets to the bone. People who drink alcohol in excess similarly develop fatty substances that may block blood vessels. Trauma, increased pressure within the bone, and other risk factors, such as radiation therapy, chemotherapy, and organ transplantation, are also related to the development of aseptic necrosis. These other risk factors need to be identified in any patient the physician prescribes steroid therapy for and appropriately balanced in terms of the risk-reward for the patient and the exposure for the physician.

The risk of suffering aseptic necrosis of the femoral head is clearly perceived to be a "rare"complication of short-term steroid therapy. At the same time, there is literature available, citing cases of aseptic necrosis of the femoral head following even low-dose, orally administered steroid medication (7 days).[5] Though McKee and his colleagues could not provide conclusive proof, there is a "cause-effect" relationship between short-course steroid therapy and aseptic necrosis of the femoral head, they noted there is "strong presumptive evidence" that an association exists between the two. This is exactly the type of statement from other colleagues that can be very problematic for the involved physician. And, obviously, it is the type of information the patient does not possess going into the physician–patient relationship. "Strong presumptive evidence," though not conclusive, can certainly provide the basis for criticism and potential exposure.

When assessing the migraine patient, it is also incumbent upon the lawyer to try to understand whether there is any specific scientific relationship between the migraineur, steroid therapy, and the risk of aseptic necrosis. In severe migraine patients, some of the literature indicates there may be objective white matter changes present in the brain. Though again the literature is sparse and the availability of scientific studies extremely limited, the issue still needs to be examined because it likely may be examined by the other side in a "medicolegal" setting. In dealing with a severe migraineur, even more caution should be applied.

In reference to defending such a prospective claim, the literature, albeit limited, can be used to support the argument the risk of developing aseptic necrosis of the femoral head is minuscule, ie, approximately 1 per 1000 patients per year. The argument that like-minded neurologists treating migraine headache subscribe to the philosophy this treatment works is also presented. The "prevailing standard of care," which is the applicable medical standard, has been arguably met if the treatment regimen utilized is the practice of competent neurologists in the involved medical community treating chronic migraine with a cervicogenic component.

A well-known analogy to "baseball" can also be successfully used to describe the proof required on behalf of the patient. The patient must prove "duty, breach, causation, and damages." The duty owed by all is to "do no harm," followed legally by the duty to meet the standard of care. If it is not met, there is a breach. And, if the breach actually causes "damages," then a claim can be successfully pursued. The patient must prove all 4; proving 2 of 4 or 3 of 4 is legally inadequate. You must "round the bases" completely in order to be successful legally.

Most importantly, the defense of what is "reasonable" is employed in this and every other potential medicolegal claim. Perfect medicine is never required, nor is perfect judgment. All that is required is to provide the level of medical care that is reasonable under the circumstances. The recommendation to be forthright and communicative is, perhaps, the best advice that can be provided to avoid exposure. After all, this is a "relationship" and such a relationship needs to be nourished. Doing so requires sharing the information the physician knows the patient lacks.

Thus, the patient in the identified example should be apprised of the risk each time steroids are prescribed. Though seemingly unnecessary, it is important to remember patients are "laymen" in the arena of medicine and their baseline of information needs to be replenished each and every time they are exposed to a risk. It takes only a couple of minutes; yet, the time invested can save, perhaps, years of heartache. Clearly, with steroid treatment, the risks increase with the passage of time. If advised each time of the risk, the patient has no excuse in the presence of a jury to deny an understanding of the choices made. The method of communicating the "risk" is, however, critical.

The "oral" informed consent involved here is inadequate. Though easier and arguably just as credible, why create the "he said, she said" scenario? Why create a question as to whether the information was relayed? Why not take a moment and provide the patient a written "explanation" of the risks and potential reward? Has the patient signed and/or initialed receipt of a reasonable explanation of the involved risks? Make it part of the chart. Doing so will effectively eliminate from this author's perspective the likelihood this patient, or any other, will create true exposure for the involved physician in a medicolegal setting. This author would certainly expect to defend any alleged misconduct successfully. Communication is key and objective documentation provides the "what if" protection that unfortunately is necessary occasionally.

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CASE 4
The Migraine That Wasn't

A 64-year-old woman presented with a history of migrainous headaches since her early 20s. Her headaches invariably had been right-sided, typically pulsatile, and at times accompanied by mild nausea, photophobia, and sonophobia. On rare occasions, the headaches were immediately preceded by photopsias, "a black spot in my vision" and "zigzags" at the left periphery. A maternal aunt and first cousin had migraine.

In the past, her headaches had failed to respond to prophylactic therapy with propranolol or amitriptyline. Acute treatment with either an oral triptan or a butalbital-containing compound had been effective in "dulling" her pain, but even so, her headaches typically persisted for an entire day.

Her past medical history was otherwise notable only for controlled hypertension. She had never had a brain imaging study.

Her general and neurologic examinations were normal.

The treating physician diagnosed her as having migraine with and without visual aura and prescribed topiramate for headache prophylaxis, along with oral rizatriptan and naproxen sodium for acute headache treatment.

At her follow-up visit 6 weeks later, she reported that her headache frequency and severity had decreased significantly subsequent to her beginning topiramate, and the oral abortive regimen had been effective in treating such breakthrough headaches as she had experienced. The treatment initially prescribed was continued.

Two weeks after that visit, she abruptly developed right-sided headache that worsened over the next few hours and was accompanied by nausea, vomiting, and progressive left body weakness. At the ED, she was noted to have a blood pressure of 171/98, to be stuporous but arousable and to exhibit right head and gaze deviation and severe left hemiparesis involving the arm and leg equally. A noncontrasted brain computerized tomography scan demonstrated evidence of intracerebral hemorrhage involving cortical and subcortical regions within the right parietal and temporal lobes, with compression of the right lateral ventricle but no intraventricular extension of the hemorrhage. A cerebral arteriogram performed 2 weeks later demonstrated a large arteriovenous malformation located within the area of hemorrhage. The patient survived but was left functionally incapacitated due to left hemineglect and left hemiparesis.

The patient's family sued the treating physician for his failure to diagnose accurately the cause of the patient's headaches and, specifically, for having failed to obtain a brain imaging study prior to the intracerebral hemorrhage.

QUESTIONS

1. *Did the treating physician's management fall below the existing standard of care by virtue of his failure to obtain a brain imaging study in advance of the intracerebral hemorrhage?*
2. *Does the existence of published "practice parameters" such as those provided by the International Headache Society serve to protect physicians in malpractice suits of the type described here?*

MEDICAL COMMENTARY

Question.—*Did the treating physician's management fall below the existing standard of care by virtue of his failure to obtain a brain imaging study in advance of the intracerebral hemorrhage?*

Answer.—No. The physician's management met the standard of care by not obtaining a scan of the brain because there was no indication for a scan. The patient had a 40-year history of migraine that improved with the physician's treatment and neuroimaging was not indicated.

The patient had a history consistent with International Headache Society second edition criteria for migraine without aura and, if the visual episodes lasted 5-30 minutes, rare migraine with aura also.[1] Should she have had a neuroimaging study? The American Academy of Neurology Quality Standards Subcommittee Guidelines state, "Neuroimaging is not usually warranted in patients with migraine and a normal neurologic examination (Grade B)."[2]

The response the medication before the treating physician first evaluated her would not be an indication for testing. Only about 50% of patients with episodic migraine respond to preventive treatment with propranol or amitriptyline. Similarly, symptomatic medications commonly only "dull" the pain without completely relieving the pain. Recall that perhaps 20% of migraineurs have no response at all to triptans. Then she was placed on topirimate for prevention and rizapatripan and naproxen sodium for symptomatic treatment with significant efficacy as is common in migraine.

Then she developed a different progressive headache with a left hemiparesis due to a bleeding large right parietal and temporal lobe arteriovenous malformation (AVM). Were there any clues in her history of the existence of the AVM?

Her headaches had always been right-sided. Is this alone suggestive of underlying pathology other than migraine? No. Her neurological examination was normal and she had no history of seizures.

Seventeen percent of those with migraine without aura and 15% of patients with migraine with aura always have headaches on the same side (side-locked headaches).[3] However, one potential migraine mimic is an AVM where side-locked headaches are present in up to 95% of cases.[4] Migraine-like headaches with and without visual symptoms can be associated with AVMs especially those in the occipital lobe which is the predominant location of about 20% of parenchymal AVMs.[5] However, typical migraine due to an AVM is the exception as there are usually distinguishing features.[6] Bruyn reported the following features in patients with migraine-like symptoms and AVM: unusual associated signs (papilledema, field cut, bruit), 65%; short duration of headache attacks, 20%; brief scintillating scotoma, 10%, absent family history, 15%; atypical sequence of aura, headache, and vomiting, 10%; and seizures, 25%. Again, this patient had no symptoms or signs to suggest an underlying AVM other than side-locked headaches which are well-described in migraineurs. She did have a left-sided visual aura but the AVM did not involve the occipital lobe.

Question.—*Does the existence of published "practice parameters" such as those provided by the International Headache Society serve to protect physicians in malpractice suits of the type described here?*

Practice parameters do not protect or indemnify the physician. However, the practice parameter, as in this case, helps to explain the physician's behavior to the jury and justify an alleged error of omission of not ordering a test. The treating physician and plaintiff expert need to simply and clearly explain to the jury why testing was not indicated. In addition, even if the AVM had been found on a magnetic resonance imaging (MRI) scan, there was no guarantee of a cure. Treatment for this large lesion would have had significant risk of morbidity and mortality, was certainly not immediately curative, and may not have even been given in time before the stroke or may have been declined by the patient.

A plaintiff expert may argue that because the plaintiff had side-locked headaches with rare left-sided visual auras, the treating physician should have had a high index of suspicion for underlying pathology such as an AVM and ordered an imaging study. The expert would also point out that the expert guideline states that neuroimaging is not usually warranted but clearly is in some cases including this one. If the unfortunate plaintiff had only had a simple 20-minute MRI scan, which has no side effects, the AVM could have been diagnosed and treated and the devastating hemorrhagic stroke would not have occurred. Plaintiff counsel would then have asked the defendant physician if she or he had ever obtained an MRI scan on a patient with migraine in the past, and if so, how often, and why? For most physicians, the answer would be yes, with some regularity. The jurors might then wonder how this plaintiff slipped through without a thorough evaluation only to suffer a terrible preventable stroke.

The treating physician and plaintiff expert then have to convince the jury of the medical facts discussed in question one—the patient had a rare incidental finding which could not have been predicted. While AVMs only occur in 0.1% of the population, 30 million persons yearly have migraines in

the United States. The lifetime prevalence of migraine is 25% in women. Certainly, everyone with a migraine does not require a scan nor does the 15% of migraineurs with side-locked headaches require a scan. In this unfortunate patient, her long history of migraines were unrelated to the AVM. Visual auras arise from the occipital lobe which was not involved in this case. The defendant physician was observing the community standard and practicing good medicine in not obtaining a scan. It is sad that she had the stroke but it was not the doctor's fault who appropriately diagnosed and treated her migraines which had been present for 40 years.

The plaintiff expert should explain that, even if the AVM had been diagnosed on MRI before bleeding, successful treatment without a neurological deficit for this large AVM was highly problematic.[7,8] The AVM may not have been treated in time. There was only 8 weeks from the time of the initial visit until the stroke. Even if a routine scan had been ordered, there may have reasonably have been a delay of a couple of weeks until it had been done. The lesion was too big for stereotactic radiosurgery. The treating physician could have chosen to refer to patient for an endovascular or neurosurgical consultation first where there may have been a several week delay for an appointment. If endovascular treatment was appropriate and chosen first, there was no certainty that the endovascular treatment would have occurred within 8 weeks after the initial physician visit or without complication.

Even if endovascular treatment was provided within 8 weeks, for a large AVM, the endovascular treatment would certainly have not been curative. To the contrary, incomplete obliteration would not change the natural history and may, in some cases, increase the risk of hemorrhage by changing the flow dynamics within the AVM.

Finally, even if the AVM had been diagnosed before bleeding, the patient may not have chosen to have treatment for the AVM. The plaintiff expert could explain to the jury how the treating neurologist, neurosurgeon, or endovascular specialist would give the patient advice for possible treatment based upon her older age, gender (females may have an increased surgical risk), annual risk of hemorrhage, and morbidity and mortality of treatment which would be greater because of the greater size of the lesion. For an unruptured AVM, the annual risk of bleeding would be 2-4%. The risk of hemorrhage from an unruptured AVM is 105 – age in years or 31% in this case. Some patients would choose not to have any treatment.[9]

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LEGAL COMMENTARY

Question.—*Did the treating physician's management fall below the existing standard of care by virtue of his failure to obtain a brain imaging study in advance of the intracerebral hemorrhage?*

Answer.—I do not believe the treating physician violated the standard of care by failing to obtain a brain imaging study prior to the intracerebral hemorrhage. Good news for the physician, but you may wonder how an attorney with no medical background can even answer the question. Using the given fact pattern, I will explain how we evaluate a potential case to determine if it has merit.

Generally, our first contact with a case is by an individual or family member who believes he or she has a potential medical malpractice claim against a healthcare provider. At its most basic level, a potential claim involves a

patient with a bad outcome and a healthcare provider who had the opportunity to prevent it. Here, the outcome left the patient functionally incapacitated. Additionally, the physician saw the patient for 2 visits prior to the bad outcome and did not diagnose the condition that led to the injury. The presented facts therefore contain the basic elements that justify an investigation into whether there is a valid malpractice claim.

The purpose of the investigation is to answer 2 questions:

1. Was the standard of care violated?
2. If so, did the standard of care violation cause the patient's injury (stated another way, if the standard of care had been met, would the injury likely have been prevented)? A negative answer to either question renders the potential claim meritless.

With respect to the first question, a common definition of the standard of care is "that degree of skill and care employed by physicians generally under similar conditions and like circumstances." We begin the investigation by having our in-house nurse search the medical literature to try to find recent journal articles and textbooks that address how physicians generally make a differential diagnosis between headache and related symptoms caused by migraines vs AVMs. Sometimes, our in-house review of the literature convinces us that there is no merit to the claim. We then advise the client of our opinion and decline further representation. We typically recommend that clients seek a second opinion, particularly when we have not had a physician review the facts. In this case, our literature search does not clearly answer the question of whether the standard of care required neuroimaging prior to the intracerebral hemorrhage.

Instead, we learn the general rule: "Neuroimaging is not usually warranted for patients with migraine and a normal neurological examination ('Grade B')."[1] However, we also learn that this rule is qualified by the recognition that "[t]esting that normally may not be recommended as population policy may make sense at an individual level. Exceptions can be considered for patients . . . about whom the provider is suspicious even in the absence of known predictors of abnormalities on neuroimaging studies (red flags)."[1] Other literature supports obtaining neuroimaging in migraineurs in patients whose headaches are always on the same side.[2-5]

Here, the patient had a history of migraines and a normal neurological examination, thus presumably putting her in the general category of patients who do not require neuroimaging. However, we must explore whether there is something particular to this patient that should have made the physician suspicious and therefore required neuroimaging studies.

This patient's headaches "invariably had been right-sided." Does this fact take her outside the general rule and support the need for neuroimaging? Given our uncertainty as to what would generally be done by physicians presented with this particular patient, we would identify physicians with expertise in headache management and retain them to review the patient's records and provide us with an opinion as to what a reasonable physician would do under these circumstances. In my analysis for this article, that is exactly what I did. I contacted a physician friend and obtained the name of a well-respected headache specialist. I contacted the specialist, provided him with the fact pattern, and questioned him about his opinions.

The specialist felt very strongly that neuroimaging was not required under these circumstances. He emphasized that this patient's presentation was extremely common. He stressed that if neuroimaging were required in this patient, it would mean that virtually all migraine patients would require neuroimaging, which he emphatically stated is not the standard of care. Further, it was his opinion that the single factor of the headaches occurring on the same side was not sufficient to require neuroimaging.

Our responsibility to our client demands that we do more than obtain expert opinions—we also must evaluate our confidence in those opinions. In this case, I was struck by the specialist's receptiveness to reviewing the case, his openness for the possibility that improper care was provided, his seeming sincerity and candor in the opinion he held, and the directness and strength of his opinion. He seemed very certain and confident of his opinion without appearing to be defensive or desirous of supporting a colleague at any cost.

Given the severity of the patient's outcome, I decided to seek a second opinion from another neurologist despite my confidence in the initial reviewer's opinion. The second opinion concurred with that of the initial reviewer. That is, he did not feel the standard of care required neuroimaging. Importantly, his analysis of the fact pattern was very consistent with the initial reviewer. Based upon the published standards and the opinion of 2 physicians, I concluded that while there was some evidence suggesting that the same-sided headaches required "consideration" of neuroimaging, this was not a sufficient "red flag" to

support an allegation that the standard of care had been violated.

Further, even assuming that the standard of care was violated, we must still investigate whether neuroimaging would have prevented the outcome. The answer here is not entirely clear. If neuroimaging had been obtained and the AVM diagnosed, the question becomes what would have been the physician's recommended course and what choice would the patient have made? The initial issue is whether therapeutic intervention would have occurred. Assuming it would have, we must understand what alternative treatments were available and the effectiveness of each treatment modality. If there was strong evidence that the standard of care was violated, and evidence that there was a reasonable opportunity for successful treatment, the uncertainty about causation would not prevent me from accepting the case. However, the minimal support for the standard of care violation and the considerable uncertainty on causation under these facts make it virtually impossible to envision the successful assertion of a claim against the physician.

Question.—*Does the existence of published "practice parameters" such as those provided by the International Headache Society serve to protect physicians in malpractice suits of the type described here?*

Answer.—Practice parameters may be helpful in defining the applicable standard of care, but they will almost never be determinative or serve to absolutely protect the physician. Practice parameters do not conclusively establish the standard of care, and compliance with them does not, in and of itself, insulate the physician from liability. The "standard of care" is somewhat of an amorphous concept. It is not something that is written in a textbook, article, policy, procedure, guideline, or practice parameter. Rather, the jury determines the standard of care and whether it was violated based upon the testimony of physicians as expert witnesses. Those physicians, testifying as experts, give an opinion as to the standard of care based on their training, education, experience, medical literature, guidelines, and practice parameters such as those published by International Headache Society.

Compliance with published practice parameters, while not insurance for the physician, generally constitutes strong evidence in his or her favor. The standard of care is simply the adherence to what is commonly done, and practice parameters by definition are published statements of what is commonly done under given circumstances. Of course, virtually every guideline or practice parameter has a disclaimer that limits its broad-based application to all conceivable circumstances. Here is an example:

> Disclaimer. This statement is provided as an educational service for the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The AAN recognizes that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.[6]

These standards were accepted in the final form on August 9, 2000. They do not mention the consideration of neuroimaging for patients with same-sided headache. Yet, in December 2006, another American Academy of Neurology publication lists same-sided headaches as a reason to consider neuroimaging in migraineurs. Under these circumstances, the plaintiff has 2 arguments to overcome the physician's compliance with the parameters. First, the practice parameter published in 2000 is by its own disclaimer incomplete. Second, the parameter is arguably inapplicable in light of subsequent publications from the same organization that add information that is seemingly inconsistent with the statement in the original parameter. The practice parameters in this case would be helpful to the physician, but would not provide any type of blanket protection for his actions.

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